Under Seal

18-CV-3775

JS 44 (Rev. 06/17) ABB

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

United States of America ex rel. S&A Litigation Partnership, LLP, et al.

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Glenn A. Ellis, Esquire - Freiwald Law, P.C.
1500 Walnut Street, 18th Floor, Philadelphia, PA 19102
215-875-8000

DEFENDANTS

Johnson & Johnson, Janssen Biotech, Inc., Johnson & Johnson Health Care Systems, Inc., Vizient, Inc., Premier, Inc., et al.

County of Residence of First Listed Defendant Essex County
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☒ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☒ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

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- ☐ 220 Foreclosure
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- ☐ 530 General
- ☐ 535 Death Penalty

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- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

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- ☐ 720 Labor/Management Relations
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- ☐ 840 Trademark

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- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
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- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
31 U.S.C. §§ 3728, et seq.

Brief description of cause:
Qui Tam case wherein Defendants used kickbacks, in violation of FCA, to induce prescribing their medications.

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

SEP - 4 2018

DATE
09/04/2018

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

Under Seal

AB

18-cv 3775

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

DESIGNATION FORM

(to be used by counsel or pro se plaintiff to indicate the category of the case for the purpose of assignment to the appropriate calendar)

Address of Plaintiff: 1925 Lovering Avenue, Wilmington, DE 19806

Address of Defendant: One J&J Plaza, New Brunswick, NJ 08933

Place of Accident, Incident or Transaction: Eastern District of Pennsylvania and Nationwide

RELATED CASE, IF ANY:

Case Number: _____ Judge: _____ Date Terminated: _____

Civil cases are deemed related when *Yes* is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court? Yes ☐ No ☑
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court? Yes ☐ No ☑
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action of this court? Yes ☐ No ☑
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual? Yes ☐ No ☑

I certify that, to my knowledge, the within case ☐ is / ☒ **is not** related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: 09/05/2018 _____ 93777

Attorney-at-Law / Pro Se Plaintiff *Attorney I.D. # (if applicable)*

CIVIL: (Place a √ in one category only)

A. Federal Question Cases:

- ☐ 1. Indemnity Contract, Marine Contract, and All Other Contracts
- ☐ 2. FELA
- ☐ 3. Jones Act-Personal Injury
- ☐ 4. Antitrust
- ☐ 5. Patent
- ☐ 6. Labor-Management Relations
- ☐ 7. Civil Rights
- ☐ 8. Habeas Corpus
- ☐ 9. Securities Act(s) Cases
- ☐ 10. Social Security Review Cases
- ☑ 11. All other Federal Question Cases
  (Please specify): False Claims Act - Qui Tam

B. Diversity Jurisdiction Cases:

- ☐ 1. Insurance Contract and Other Contracts
- ☐ 2. Airplane Personal Injury
- ☐ 3. Assault, Defamation
- ☐ 4. Marine Personal Injury
- ☐ 5. Motor Vehicle Personal Injury
- ☐ 6. Other Personal Injury *(Please specify):* _____
- ☐ 7. Products Liability
- ☐ 8. Products Liability – Asbestos
- ☐ 9. All other Diversity Cases
  (Please specify): _____

ARBITRATION CERTIFICATION

(The effect of this certification is to remove the case from eligibility for arbitration.)

I, Glenn A. Ellis, counsel of record *or* pro se plaintiff, do hereby certify:

☑ Pursuant to Local Civil Rule 53.2, § 3(c) (2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of $150,000.00 exclusive of interest and costs:

☐ Relief other than monetary damages is sought.

SEP - 4 2018

DATE: 09/05/2019 _____ 93777

Attorney-at-Law / Pro Se Plaintiff *Attorney I.D. # (if applicable)*

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

Civ. 609 (5/2018)

Under Seal

AB

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

United States of America, *ex rel.* S&A Litigation Partnership, LLP, et al	:	CIVIL ACTION
v.	:	
Johnson & Johnson, Janssen Biotech, Inc., Johnson & Johnson Health Care Systems, Inc., Vizient, Inc., et al	:	NO. 18cv3775

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

(a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )

(b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )

(c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )

(d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )

(e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) (X)

(f) Standard Management – Cases that do not fall into any one of the other tracks. ( )

September 5, 2018		S& A Litigation Partnership, LLP
Date	**Attorney-at-law**	**Attorney for**
215-875-8000	215-875-8575	gae@freiwaldlaw.com
Telephone	**FAX Number**	**E-Mail Address**

(Civ. 660) 10/02

SEP - 4 2018

FREIWALD LAW
TRIAL LAWYERS
Glenn A. Ellis
gae@freiwaldlaw.com

DOCUMENT TO BE FILED UNDER SEAL

September 4, 2018

VIA HAND DELIVERY
Clerk, United States District Court for Eastern District of Pennsylvania
601 Market Street
Room 2609
Philadelphia, PA 19107

Re: United States of America, ex re. S&A Litigation Partnership, LLP v. Johnson & Johnson, et al.

Dear Clerk:

Enclosed are an original and one (1) copy of a Complaint that needs to be filed under seal pursuant to 31 U.S.C. § 3730 (b)(2).

This firm's draft in the amount of $400.00 made payable to the Clerk, United States District Court is enclosed as your filing fee. A self-addressed, stamped envelope is also enclosed for your convenience to return the time-stamped copy to our office.

Very truly yours,

GLENN A. ELLIS

GAE/jae
Enclosure

FILED UNDER SEAL

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

PLAINTIFFS UNDER SEAL

v.

DEFENDANTS UNDER SEAL

Civil Action No. 18cv3775

FILED BY HAND

FILED UNDER SEAL

JURY TRIAL DEMANDED

FILED
SEP 4 2018
KATE BARKMAN, Clerk
By Dep. Clerk

COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS UNDER 31 U.S.C. §§ 3729 *ET SEQ.*, STATE LAW COUNTERPARTS AND THE CALIFORNIA INSURANCE FRAUD PREVENTION ACT

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *ex rel.* S&A LITIGATION PARTNERSHIP, LLP, and on behalf of the STATES of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW HAMPSHIRE, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, WASHINGTON, the Commonwealth of MASSACHUSETTS, the Commonwealth of VIRGINIA, the DISTRICT OF COLUMBIA, and the PEOPLE OF CALIFORNIA, Plaintiffs, v. JOHNSON & JOHNSON, JANSSEN BIOTECH, INC., JOHNSON & JOHNSON HEALTH CARE SYSTEMS, INC. VIZIENT, INC., PREMIER, INC., HEALTHTRUST PURCHASING GROUP, L.P., INTALERE, INC., ASEMBIA, LLC, and JOHN DOE HEALTH CARE PROVIDERS #1-1000, FICTITIOUS NAMES, Defendants.	Civil Action No. _____ **FILED BY HAND** **FILED UNDER SEAL** **JURY TRIAL DEMANDED**

COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS UNDER 31 U.S.C. §§ 3729 *ET SEQ.*, STATE LAW COUNTERPARTS AND THE CALIFORNIA INSURANCE FRAUD PREVENTION ACT

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BARON & BUDD, P.C.
W. Scott Simmer, D.C. Bar #46072
Andrew M. Miller, D.C. Bar #499298
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600 New Hampshire Avenue, NW, Suite 10-A
Washington, DC 20037
Telephone: (202) 333-4562
Facsimile: (202) 337-1039

Attorneys for Relator

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COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS UNDER 31 U.S.C. §§ 3729 ET SEQ., STATE LAW COUNTERPARTS AND THE CALIFORNIA INSURANCE FRAUD PREVENTION ACT

This is an action brought by S&A LITIGATION PARTNERSHIP, LLP ("Relator") on behalf of the United States of America, the Whistleblower States and the People of California against JOHNSON & JOHNSON, JANSSEN BIOTECH, INC., and JOHNSON & JOHNSON HEALTH CARE SYSTEMS, INC. (collectively, "J&J," "the Company"); VIZIENT, INC., PREMIER, INC., HEALTHTRUST PURCHASING GROUP, L.P., INTALERE, INC., and ASEMBIA, LLC (collectively, the "GPO Defendants"); and JOHN DOE HEALTH CARE PROVIDERS #1-1000 (J&J, the GPO Defendants and the John Doe Health Care Providers, all collectively "the Defendants"); pursuant to the *qui tam* provisions of the federal Civil False Claims Act, 31 U.S.C. § 3729, *et seq.*; pursuant to the *qui tam* provisions of: the California False Claims Act, Cal. Gov't Code §§ 12650 *et seq.* (Deering 2000); the Colorado Medicaid False Claims Act, Colo. Rev. Stat. §§ 25.5-4-304 *et seq.* (2010); the Connecticut False Claims Act, Conn. Gen. Stat. tit. 4 Ch. 55e §§ 4-274 *et seq.* (2014); the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, §§ 1201 *et seq.* (2013); the District of Columbia False Claims Act, D.C. Code §§ 2-308.13 *et seq.* (2013); the Florida False Claims Act, Fla. Stat. tit. 6, §§ 68.081 *et seq.* (2000); the Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 *et seq.* (2013); the Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21 *et seq.* (2012); the Illinois False Claims Act, 740 Ill. Comp. Stat. §§ 175/1 *et seq.* (2012); the Indiana Medicaid False Claims and Whistleblower Protection Act, Ind. Code §§ 5-11-5.7 *et seq.* (2014); the Iowa False Claims Act, Iowa, tit. 15 §§ 685.1 *et seq.* (2011); the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. §§ 46:437.1 *et seq.* (2011); the Maryland False Health Claims Act, MD, tit. 2 §§ 2-601 *et seq.* (2012); the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, §§ 5A *et*

seq. (2013); the Michigan Medicaid False Claims Act, Mich. Comp. Laws §§ 400.601 *et seq.* (2009); the Minnesota False Claims Act, Minn. Stat. §§ 15C.01 *et seq.* (2013); the Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 *et seq.* (2005); the Nevada False Claims Act, Nev. Rev. Stat. §§ 357.010 *et seq.* (2013); the New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 *et seq.* (2009); the New Hampshire False Claims Act, NH Stat. Ann §§ 167:61-b *et seq.* (2005); the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1 *et seq.* (2007); the New York False Claims Act, N.Y. State Fin. Law Art. XIII §§ 187 *et seq.* (McKinney 2013); the North Carolina False Claims Act, N.C. Gen. Stat. §§ 1-605 *et seq.* (2010); the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, §§ 5053 *et seq.* (2009); the Rhode Island False Claims Act, R.I. Gen. Laws §§ 9-1.1-1 *et seq.* (2013); the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 *et seq.* (2006); the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. §§ 36.001 *et seq.* (2013); the Texas Medical Assistance Program, Damages, and Penalties Act, Tex. Hum. Res. Code. Ann. § 32.039 *et seq.* (2007); the Vermont False Claims Act, Vt. tit. 32 VSA §§ 632 *et seq.* (2015); the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 *et seq.* (2012); the Washington State Medicaid False Claims Act, RCW 74.66.005 *et seq.* (2016) (state law claims collectively, the "state whistleblower statutes" or "Whistleblower States"); and pursuant to the California Insurance Fraud Prevention Act ("CIFPA"), Cal. Ins. Code § 1871.7.

I. INTRODUCTION

1. Relator brings this action on behalf of the United States, the Whistleblower States, and the People of California to recover damages and civil penalties under the False Claims Act, state whistleblower statutes, and the CIFPA against Defendants for causing the submission of

false or fraudulent claims; for making, using, or causing to be made or used false records or statements material to false or fraudulent claims; and for conspiring to do all of the same.

2. This case is about J&J's efforts to bribe the Health Care Providers to maintain its stranglehold in respect of an important biologic, brand named Remicade, also known by its generic name, infliximab, and pay illegal kickbacks for conversion of Remicade scripts to its drug Simponi Aria.

3. J&J has paid illegal kickbacks to induce physicians, the GPO Defendants, home infusion companies, and stand-alone infusion centers[1] (collectively, the "Health Care Providers") to purchase and prescribe its drugs Remicade and Simponi Aria, in violation of the federal Anti-Kickback Statute ("AKS") and State anti-kickback laws, which were enacted to protect patients and health care programs from fraud and abuse by curtailing the pernicious and corrupting influence of bribes on health care decisions.

4. From 1998 until it lost its Remicade patent in 2016, J&J has owned patents protecting Remicade and has been amply rewarded for its invention: Between 1998 and 2016, Remicade was the only infliximab product on the market. This position allowed Remicade to become J&J's best-selling drug by far, generating $4.8 billion in U.S. sales in 2016 alone. Indeed, during this time Remicade has become among the best-selling drugs in the world.

5. Remicade is expensive. For most uses, at list price Remicade sells for about $4,000 per infused dose and about $26,000 for a full year of treatment.

[1] Prior to the 1980s, patients typically received infusion therapy in an inpatient setting at a hospital, nursing home, or other long-term care facility for the duration of their therapy. With technological developments in infusion therapy and a greater preference on reducing costs led to the rise of home infusion companies and stand-alone infusion centers. These companies and centers can reduce costs for infusion therapy, particularly for patients, in part by not charging facility fees. The home infusion therapy market is estimated to capture at least $11 billion in annual spending in the U.S. alone.

6. When competing Remicade biosimilars first appeared in 2016, J&J deployed tactics to maintain the dominance of its flagship product and in January 2018 began its illegal scheme to hold onto its Remicade sales while converting patients to its patent-protected product, Simponi Aria.

7. Although J&J knew that the AKS and state analogues prohibited it from giving kickbacks to Health Care Providers to purchase and prescribe Remicade and Simponi Aria, it disregarded that prohibition, choosing instead to put sales growth and profits before its duty to comply with federal and state laws. Specifically, from January 2018 until the present, J&J has offered kickbacks to the Health Care Providers in order to influence whether its Remicade, Simponi Aria, or a competitor's drug was prescribed to patients. These Health Care Providers agreed to disregard their professional independence and use their influence (a) to continue dispensing Remicade instead of competitor drugs, which were often cheaper and/or more effective, (b) lock in Remicade and Simponi Aria purchase levels where they were a year prior, and (c) to switch patients from Remicade to either Simponi Aria (which J&J referred to as "conversion").

8. In furtherance of the kickback scheme, J&J and the Health Care Providers concealed key aspects of their relationships from patients and the Government.

- *First*, when the Health Care Providers, in exchange for kickbacks from J&J, recommended switching patients from Remicade to either Simponi Aria or opposed the use of Remicade biosimilar drugs or cheaper, equally (or often more) effective drugs, they presented those recommendations to patients as unbiased professional opinions, without disclosing that they stood to earn tens or hundreds of thousands of dollars from J&J as a result of those recommendations.

- *Second*, although J&J drafted rebate contracts for the parties to sign, these written agreements invariably omitted the unlawful promises that J&J had extracted in exchange for J&J's payments – i.e., to switch patients from Remicade to either Simponi Aria or to keep recommending and dispensing Remicade.
- *Third,* no Government Program beneficiary benefited financially from these rebates or other monies paid to the Health Care Providers, instead they were potentially responsible for up to 20 percent on the entire cost of these very expensive drugs.
- *Fourth,* the illegal inducement from J&J was not disclosed in the J&J agreements with the Health Care Providers, nor was it disclosed in the invoices J&J sent to the Health Care Providers along with the rebate payments, nor did the Health Care Providers in turn "appropriately reflect" the remuneration in their billing to Government Programs.
- *Finally,* to ensure that it would reap the Remicade and Simponi Aria sales produced by kickbacks, J&J also ignored compliance issues raised by the kickback arrangement in violation of its own written policies and procedures, as well as its reporting obligations under its Corporate Integrity Agreement with the United States. J&J executives disregarded reporting requirements under the company's compliance policies, failing to report the obvious compliance issues raised by an effort to induce conversion of patients from Remicade to Simponi Aria in exchange for bribes.

9. J&J and the Health Care Provider Defendants knew that some 40 percent of the patients being treated with Remicade or Simponi Aria were Government Program Beneficiaries,

and J&J thus intended that its provision of illegal bribes was contingent upon, and would induce, the Health Care Providers to prescribe these drugs to Government Program Beneficiaries. The claims for these Government Program Beneficiaries were submitted by the Health Care Providers and were tainted by kickbacks, making them false claims. These claims were in turn reimbursed or paid for by Government Programs, such as Medicaid and Medicare, in lieu of cheaper, equally effective Remicade biosimilars and/or other drugs.

10. J&J and the Health Care Providers have violated federal AKS and state analogues, as well as the federal False Claims Act, the state False Claims Acts and the CIFPA, and in so doing, have deceived the federal Government, the Whistleblower States and California MCOs into paying hundreds of millions of dollars in prescription drug claims that were not eligible for reimbursement.

11. In order to execute its unlawful conduct, J&J needed to conceal its illegal conduct from Government oversight, particularly in light of the fact that since 2014 it had been operating under a Corporate Integrity Agreement ("CIA").

12. J&J engaged in a deliberate plan to knowingly submit false reports to the Office of the Inspector General ("OIG")—as required per the terms of each CIA—that either materially misrepresented the facts concerning its illegal conduct or concealed such conduct altogether. As such, J&J knowingly made, used, or caused to be made or used, false records or statements material to an obligation to pay or transmit money or property to the Government, and/or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government.

13. J&J's employees were aware of the CIA, as the CIA required a written Code of Conduct be distributed to all Covered Persons, and each Covered Person was required to certify,

in writing, that he or she had received, read, understood, and would abide by this Code of Conduct. As alleged herein, J&J's employees failed to report what they knew were violations of its Code of Conduct.

14. This conduct is ongoing.

II. JURISDICTION AND VENUE

15. This Court has subject matter jurisdiction over this action pursuant to 31 U.S.C. § 3732(a), 28 U.S.C. § 1331, and 28 U.S.C. § 1345. The Court has original jurisdiction over the state law claims pursuant to 31 U.S.C. § 3732(b) because this action is brought under state laws for the recovery of funds paid as the result of kickbacks and arises from the same transaction or occurrence brought on behalf of the United States under 31 U.S.C. § 3730 and 28 U.S.C. § 1367.

16. This Court has personal jurisdiction over the Defendants because, among other things, Defendants transact business in this District and engaged in wrongdoing in this District.

17. Venue is proper in this District under 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b) and (c). Defendants transact business within this District and acts proscribed by 31 U.S.C. § 3729 occurred in this District.

18. The causes of action alleged herein are timely brought because, among other things, of efforts by the Defendants to conceal from the United States, the States and the People of California their wrongdoing in connection with the allegations made herein.

19. As alleged in this Complaint, Defendants have been engaged in a multi-faceted, nationwide, unlawful kickback scheme involving its sales and marketing employees across the United States, including in each of the Whistleblower States and the State of California.

III. PERFECTION OF FILING AND STANDING TO REPRESENT THE UNITED STATES, THE QUI TAM STATES, AND THE PEOPLE OF THE STATE OF CALIFORNIA

20. This Complaint was properly filed in camera and under seal, as required by the False Claims Act, the state *Qui Tam* statutes, and the CIFPA, and shall remain under seal for at least sixty days as required by said provisions.

21. Contemporaneous with the filing of the original Complaint, Plaintiff properly served a copy of the complaint and written disclosure of substantially all material evidence and information upon the United States, the *Qui Tam* States, the California district attorney and the insurance commissioner.

22. Plaintiff is not aware of any "public disclosure," as that term is used in the FCA, the state *Qui Tam* statutes, or in the CIFPA, of the allegations forming the core elements of the Counts against Defendants.

23. In the event there is found to be any such public disclosure, Plaintiff alleges that it is an "original source," as that term is used in the FCA, the state *Qui Tam* Statutes and/or the CIFPA, of the allegations or transactions forming the core elements of the cause(s) of action against Defendants.

24. In particular, consistent with the meaning of "original source" under the FCA, the state *Qui Tam* statutes and the CIFPA, Plaintiff has direct and independent knowledge of the information on which the allegations are based, and voluntarily provided the information to the district attorney or commissioner before filing this action.

IV. PARTIES

A. PLAINTIFF/RELATOR

25. Relator S&A Litigation Partnership, LLP, a Delaware limited liability partnership, brings this action on behalf of itself, the United States of America, the Whistleblower States, and the People of California. The registered office of the Relator is 1925 Lovering Avenue,

Wilmington, Delaware 19806, and the name of the registered agent at such address is The First State Registered Agent Company.

26. Pursuant to Section 15-201(a) of the Delaware Revised Uniform Partnership Act, S&A Litigation Partnership, LLP is not distinct from its partners, who, by virtue of their employment with J&J, at all times material hereto have had firsthand, personal knowledge of the false claims, statements, and concealments alleged herein.

27. S&A Litigation Partnership, LLP and its partners have direct knowledge of the conduct alleged in this Complaint and conducted an independent investigation to uncover false claims submitted to the United States, the Whistleblower States and California MCOs. Accordingly, Relator is an "original source" of the non-public information alleged in this Complaint within the meaning of the federal False Claims Act, state False Claims Acts, and the CIFPA.

B. J&J DEFENDANTS

28. Defendant Johnson & Johnson is a corporation organized and existing under the laws of New Jersey. Johnson & Johnson's principal place of business in the United States is located at One J&J Plaza, New Brunswick, NJ 08933. Johnson & Johnson is an international pharmaceutical company—one of the largest in the world—and was the sole supplier of infliximab, marketed as Remicade, from 1998 until 2016, when Remicade biosimilars first came to market.

29. Janssen Biotech, Inc. ("Janssen") is a wholly owned subsidiary of Johnson & Johnson. Janssen is a corporation organized and existing under the laws of Pennsylvania. Janssen's corporate headquarters are located at 800 Ridgeview Drive, Horsham, PA 19044.

Janssen co-owns or has licenses to the Remicade patents and performs the marketing for Remicade in the United States.

30. Johnson & Johnson Health Care Systems, Inc. ("JJHCS") is a wholly owned subsidiary of Johnson & Johnson. JJHCS is a corporation organized and existing under the laws of Pennsylvania with corporate offices located in Piscataway, NJ. JJHCS offers logistic services to transport cardiology, orthopedics, minimally invasive surgery, and diagnostics products that are used to diagnose and treat patients with serious life threatening and debilitating diseases. It also is the party which enters into the Contract Purchase Program deals alleged herein.

31. Johnson & Johnson, Janssen Biotech, Inc., and Johnson & Johnson Health Care Systems, Inc. shall be referred to herein collectively as "J&J" or "the Company."

C. THE GPO DEFENDANTS

32. Vizient Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business located at 290 E. John Carpenter Freeway, Irving, TX 75062. The company represents the integration of VHA Inc., University Health System Consortium, and Novation as of April 1, 2015, and the subsequent acquisition of MedAssets' Spend and Clinical Resource Management segment, including Sg2, on February 15, 2016. Vizient's predecessors began operating as a GPO for supply contracting beginning in 1979. Vizient is the nation's largest GPO, representing more than 50% of the annual spending of United States health care providers on medical devices and supplies. It brokers more than $100 billion in sales annually.

33. Premier Inc. is a corporation organized and existing under the laws of Delaware with corporate headquarters located at 13034 Ballantyne Corporate Place, Charlotte, NC 28277. Premier consists of an alliance of approximately 3,900 U.S. hospitals and health systems and approximately 150,000 other providers and organizations. Premier's GPO purchasing volume is

approximately $56 billion. Premier is the nation's second largest GPO, representing more than 25% of the annual spending of United States health care providers on medical devices and supplies.

34. HealthTrust Purchasing Group, L.P. is a corporation organized and existing under the laws of Delaware with its principal place of business located at 155 Franklin Road, Suite 400, Brentwood, TN 37027. HealthTrust Purchasing Group, LP provides consulting, managed, or outsourcing services to health care providers. HealthTrust Purchasing Group, LP operates as a subsidiary of Parallon Business Solutions, LLC.

35. Intalere, Inc., formerly Amerinet, is a corporation organized and existing under the laws of Delaware with its principal place of business at Two CityPlace Drive, Suite 400, St. Louis, MO 63141. Intalere is a professional supply chain company that is now substantially owned by Intermountain Healthcare of Salt Lake City. Intermountain Healthcare is a not-for-profit system of 22 hospitals, more than 185 physician clinics, a health plans division called SelectHealth, and other health services with more than 37,000 employees. The company was founded in 1986. As of July 1, 2018, Intalere's members included nearly 4,000 acute care hospitals, approximately 42,000 clinics, approximately 13,000 long-term care facilities, and over 40,000 other centers and physicians. Intalere's purchasing volume as of 2017 was $7.6 billion.

36. Asembia, LLC is a limited liability corporation organized and existing under the laws of Delaware with its principal place of business located at 200 Park Avenue, Suite 300, Florham Park, NJ 07932. Originally founded as Armada Health Care in 2004, Asembia was the first organization to establish and promote specialty pharmacy as a distinct trade class and formed its GPO to service that market. Asembia's members include specialty pharmacies, alternate care pharmacies, health systems, retail pharmacies, and prescribers.

D. DEFENDANTS JOHN DOE HEALTH CARE PROVIDERS #1-1000

37. John Doe Health Care Providers #1-1000, fictitious names, are unnamed Health Care Providers who are individuals, corporations, limited liability companies, and/or other lawful business entities with which J&J does business in the United States, and who are known or unknown co-conspirators who conspired with J&J to perpetuate the kickback schemes alleged herein.

38. To the extent that any of the conduct alleged in this Complaint was not performed by the named Defendants, but by the unnamed Health Care Providers, individuals or entities alleged herein as John Doe Health Care Providers #1-1000, fictitious names, any reference herein to Defendants under such circumstances, and only under such circumstances, refers also to the Defendant John Doe Health Care Providers #1-1000 and/or other co-conspirators who conspired with Defendants to perpetrate the schemes alleged herein.

V. BACKGROUND OF THE REGULATORY FRAMEWORK

A. BIOLOGICS

39. Most well-known pharmaceutical products, like aspirin, are "small molecule drugs." These drugs contain active ingredients having well-defined, precise chemical structures. Scientists can synthesize these molecules in a laboratory using well-understood chemical reactions. A party may not sell a new small molecule containing drug in the United States until the FDA approves a New Drug Application ("NDA") for that drug. The new drug applicant must support its NDA with extensive data from clinical trials that demonstrate the drug's safety and efficacy. *See* 21 U.S.C. §§ 355(b)(1), (d)(1)-(7). A party wishing to sell a drug that is identical to an already approved drug does not have to repeat the extensive clinical trials or submit an NDA. Instead, that party may submit an Abbreviated New Drug Application ("ANDA") seeking

approval to sell a generic version of the drug. Because the generic drug contains an active ingredient identical to the active ingredient in the approved drug, the ANDA applicant can rely on the data in the relevant NDA and need only show that its proposed generic drug has the same active ingredient, strength, dosage form, and route of administration as the approved product, and thus is bioequivalent to that approved product. 21 U.S.C. § 355(j)(2).

40. Over the past few decades, in addition to new small molecule drugs, innovative companies have developed and commercialized new biologic therapeutics ("biologics"). Unlike small molecule containing drugs, biologics are treatments derived from living systems such as microorganisms or plant or animal cells. As the FDA explains: "Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues."[2]

41. Biologics are isolated from a variety of natural sources—human, animal, or microorganism—and may be produced by biotechnology methods and other cutting-edge technologies. Gene-based and cellular biologics, for example, often are at the forefront of biomedical research, and may be used to treat a variety of medical conditions for which no other treatments are available.[3] In contrast to most drugs, "which are chemically synthesized and whose structure is known, most biologics are complex mixtures that are not easily identified or characterized.[4]

B. FDA REGULATION OF BIOLOGICS AND BIOSIMILARS

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[2] *See* U.S. Food & Drug Administration, *What Are "Biologics" Questions and Answers*, https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cber/ucm133077.htm.
[3] *Id.*
[4] *Id.*

42. Congress has made clear that access to cheaper equivalent generic pharmaceuticals should be encouraged, and, to that end, in 1984 enacted the Hatch-Waxman Act ("Hatch-Waxman"), which established an abbreviated pathway for approval of generic counterparts to non-biologic branded drug products. Before Hatch-Waxman, a generic applicant had to conduct the same kinds of safety and efficacy studies (including large clinical trials and the like) as the originating drug manufacturer. Such a process, which can cost hundreds of millions of dollars and take years to complete, was prohibitive for would-be generic entrants and led to the near absence of generic competition to branded drug products.

43. A principal goal of Hatch-Waxman was to trigger generic access to originator products, many of which had enjoyed longstanding exclusivity. That goal has been achieved: According to the FDA, the competition spurred by Hatch-Waxman has from 2006 to 2016 saved more than $1.6 trillion for patients and the health care system.[5]

44. However, for a number of reasons, biologic products generally have not been covered by the Hatch-Waxman procedures. Nevertheless, given the success of Hatch-Waxman in spurring generic access for non-biologic medicines, Congress and nearly all stakeholders in the health care system have recognized the great desirability of having an analogous system for biologics.[6]

45. In 2009, Congress addressed the need for competition in the biologics marketplace by introducing the Biologics Price Competition and Innovation Act ("BPCIA"),

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[5] *See* Kathleen "Cook" Uhl, *2016: A Record-Setting Year for Generic Drugs, U.S. Food & Drug Administration* (Feb. 24, 2017), available at https://blogs.fda.gov/fdavoice/index.php/2017/02/2016-arecord-setting-year-for-generic-drugs/ (noting that "2016 was a record-setting year for FDA's generic drug program," and that "[o]ver the last 10 years, generic drugs have saved the U.S. healthcare system about $1.68 trillion").

[6] *See* U.S. Food & Drug Administration, *Implementation of the Biologics Price Competition and Innovation Act of 2009* (Feb. 12, 2016), available at https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/ucm215089.htm ("The goal of the BPCI Act is similar, in concept, to that of the Drug Price Competition and Patent Term Restoration Act of 1984 (a.k.a. the 'Hatch-Waxman Act') which created abbreviated pathways for the approval of drug products under federal Food, Drug, and Cosmetic Act (FFD&C Act).").

which was signed into law in 2010. The Act furthers the "FDA's longstanding policy of permitting appropriate reliance on what is already known about a drug, thereby saving time and resources and avoiding unnecessary duplication of . . . testing."[7]

46. A principal purpose of the Act—as reflected in its name—was to encourage the availability of cheaper "biosimilar" drug products:

- "We have to find a way to introduce competition into [the biosimilar] market," including balancing "giving incentives for development of new products but bringing about the benefits of competition in the marketplace." (Hon. Henry Waxman, United States Representative from California)
- "Legislation to facilitate the development of biosimilars should promote competition and lower prices[.]" (Hon. Anna G. Eshoo, United States Representative from California)
- "We want to foster a robust biosimilar market." (Hon. Joe Barton, United States Representative from Texas)
- "[C]ompetition [from biosimilars] is good for patient safety, consumer choice, and drive[s] savings for consumers and the healthcare system at large." (Hon. Gene Green, United States Representative from Texas)

47. The BPCIA provides an abbreviated regulatory approval pathway for the introduction of biosimilars. A biosimilar applicant may rely on the clinical studies of the reference listed drug if it can show: (a) that the proposed biosimilar is "highly similar to the [originator product, or RLD] notwithstanding minor differences in clinically inactive

[7] U.S. Food & Drug Administration, *Implementation of the Biologics Competition and Innovation Act of 2009*, https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm215089.htm (last visited Sept. 18, 2017).

components"; and (b) that "there are no clinically meaningful differences between the [proposed biosimilar] and the [RLD] in terms of safety, purity, and potency." 42 U.S.C. § 262(i)(2).

48. Although biosimilars have no clinically meaningful differences in safety, purity, and potency from the RLD, they are not automatically substitutable with the RLD (unlike Hatch-Waxman generics). Thus, if a doctor prescribes the RLD, a pharmacist cannot substitute a biosimilar unless that product has been designated as interchangeable by FDA and the relevant state law permits substitution of interchangeable biologics.[8] This allows originator firms to retain the bulk of their existing patient bases, which typically is not possible for a branded firm to do when a Hatch-Waxman generic enters (because state substitution laws permit prescriptions for the brand to be automatically substituted with the Hatch-Waxman generic by the pharmacist without the need for physician intervention).

49. Even though the biosimilar pathway has been available in the U.S. since 2009, the growth of the biosimilars market has been much slower than had been estimated. In 2009, the Congressional Budget Office (CBO) had predicted a 10-year decrease in federal spending of $5.9 billion attributable to "follow on biologics"/biosimilars, with ~50% of those savings in Medicare Part B (i.e., $3 billion). One source shows the actual annual biosimilar savings in 2018 at only $91 million, just 9% of the CBO's estimated 2018 savings of $1 billion.[9] This suggests that the market is behaving much differently than expected at the time that Congress implemented the biosimilar pathway.

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[8] The BPCIA does provide for an "interchangeable" designation, but FDA published draft guidelines for establishing interchangeability only in 2017. U.S. Food & Drug Administration, *Considerations in Demonstrating Interchangeability With a Reference Product* (Draft Guidance) (Jan. 17, 2017). Nonetheless, neither the BPCIA nor FDA contemplates that biosimilars should be prevented from competing in the marketplace—i.e., that consumers should be denied access to them—until they are designated interchangeable.

[9] Avalere, *Use of Step Through Policies for Competitive Biologics Among Commercial US Insurers*, available at http://go.avalere.com/acton/attachment/12909/f-0552/1/-/-/-/-/Use%20of%20Step%20Through%20Policies%20for%20Competitive%20Biologics%20Among%20Commercial%20US%20Insurers.pdf

50. The Commissioner for the FDA, Scott Gottlieb, has been openly critical of "Big Pharma" efforts to impede access to biosimilars, denouncing "rebating schemes" in which drug makers bundled discounts for health insurers and employers—which are represented by pharmacy benefit managers—in ways that discourage coverage of lower-priced biosimilars.[10]

C. PHYSICIANS MUST SUBMIT TRUE AND ACCURATE CLAIMS AND CORRECT ANY KNOWN FALSE STATEMENTS

51. Federal law specifically prohibits physicians from making "any false statement or representation of a material fact in any application for any ... payment under a federal healthcare program." *See* 42 U.S.C. §1320-a-7b(a)(l).

52. Similarly, federal law requires physicians who discover material omissions or errors in claims submitted to Medicare, Medicaid, or other federal health care programs to disclose those omissions or errors to the Government. *See* 42 U.S.C. §1320-a-7b(a)(3). The requirement that physicians be truthful in submitting claims for reimbursement is a precondition for participation in the Medicare program, the Medicaid program, and other federal and state-funded health care programs. *See, e.g.,* 42 CFR §§ 1003.105, 1003.102(a)(l)-(2).

D. THE ANTI-KICKBACK STATUTE ("AKS")

53. The federal health care AKS, 42 U.S.C. §1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any

[10] Jeff Overley, *FDA Chief Blames Big Pharma For 'Anemic' Biosimilars Sales*, Law360 (July 17, 2018), available at https://www.law360.com/lifesciences/articles/1064630/fda-chief-blames-big-pharma-for-anemic-biosimilars-sales?nl_pk=9380bba6-d61d-45f1-b1d1-ecca6b5c9ed9&utm_source=newsletter&utm_medium=email&utm_campaign=lifesciences

form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.

54. The AKS and analogous state statutes prohibit any person or entity from making or accepting payment to induce or reward any person for referring, recommending, or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. § 1320a-7b(b). Under this statute, drug companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce health care providers or others to order or recommend drugs that may be paid for by a federal health care program. The law not only prohibits outright bribes and rebate schemes, but also prohibits any payment by a drug company in cash or in kind that has as one of its purposes to induce a physician to write additional prescriptions for the company's pharmaceutical products.

55. In relevant part, the AKS states:

> [W]hoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person--
>
> > (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a federal health care program, or
> >
> > (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b)(2).

56. AKS promulgating regulations directly prohibit any provider from receiving remuneration paid with the intent to induce referrals that take into account the "volume or value" of any referrals or business generated. *See* 42 C.F.R. § 1001.952(f)(2). Such remuneration

amounts to a kickback and can increase the expenditures paid by Government-funded health benefit programs by leading to over-utilization of certain products or services, inducing medically unnecessary and excessive reimbursements. Kickbacks also effectively reduce patients' health care choices, because unscrupulous (or unknowing) physicians steer their patients to various products or services based on the physicians' own interests rather than the patients' medical needs.

57. Violation of the AKS subjects the violator to exclusion from participation in federal health care programs, civil monetary penalties, and imprisonment of up to five years per violation. 42 U.S.C. §§ 1320a-7(b)(7), 1320a-7a(a)(7).

58. Concern about improper drug marketing practices like those alleged in this Complaint prompted the Inspector General of the Department of Health and Human Services ("HHS") to issue a Special Fraud Alert in 1994 identifying prescription drug marketing practices that violate the Anti-Kickback law. Special Fraud Alert: Prescription Drug Marketing Schemes, 59 Fed. Reg. 65,376 (Dec. 19, 1994). Among the suspect practices cited by the Inspector General were payments or gifts to physicians who had offered no particular services of benefit to the drug company, but who had generated in the past, or had the potential to generate in the future, a large volume of business for the drug company. *Id.*

E. THE AKS PROHIBITS DRUG MAKER PRODUCT CONVERSION PROGRAMS

59. As early as 1994, the Government made clear that the AKS prohibits drug manufacturers from offering financial incentives to pharmacies to effectuate "product conversion" programs where even one purpose is to induce increased use of prescription drugs covered by federal health care programs. Specifically, HHS-OIG issued "Special Fraud Alerts," explaining that

> In recent years, prescription drug companies in the United States have increased their marketing activities among providers, patients and suppliers such as pharmacists .... Traditionally, physicians and pharmacists have been trusted to provide treatments and recommend products in the best interest of the patient. In an era of aggressive drug marketing, however, patients may now be using prescription drug items, unaware that their physician or pharmacist is being compensated for promoting the selection of a specific product.[11]

One of the examples provided was of a "product conversion" program in which a drug company provided pharmacies cash awards for changing from a competitor's product to that drug company's product; in this scenario, "[t]he pharmacies were induced to help persuade physicians, who were unaware of the pharmacies' financial interest, to change prescription."[12]

60. In May 2003, the Inspector General of HHS released a further Guidance identifying in greater detail several marketing practices of drug manufacturers that constitute "kickbacks and other illegal remuneration" infecting federal health care programs.[13] The 2003 Guidance cautions manufacturers that any time a manufacturer provides anything of value to a physician who might prescribe the manufacturer's product(s), the manufacturer should examine whether it is providing a valuable tangible benefit to the physician with the intent to induce or reward referrals. The OIG Guidance lists the following, among others, as suspect practices: "Improper Switching Arrangements: These are arrangements by which pharmaceutical manufacturers offer physicians cash or other benefits to change prescriptions from a competitor's product to the manufacturer's product."[14]

F. COMPLIANCE WITH THE AKS IS A PRECONDITION TO PARTICIPATION IN GOVERNMENT PROGRAMS

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[11] 59 Fed. Reg. at 65,376 (Dec. 19, 1994).
[12] *Id.*
[13] 68 Fed. Reg. 23731 (May 5, 2003) (Office of Inspector General, HHS, Compliance Program Guidance for Pharmaceutical Manufacturers).
[14] *Id.* at 23731-39.

61. Compliance with the AKS is a precondition to participation as a health care physician under Medicare Advantage, Medicare Part B, the Indian Health Service, Medicaid, the Mail Handler's Health Benefit Plan, the U.S. Secret Service Employees Health Association Health Benefit Plan, TRICARE, and the Veteran's Health Administration ("VHA"), as well as state employee health plans, state medical assistance programs, and/or state-provided medical care in prisons, hospitals and clinics (collectively, the "Government Programs").

62. With regard to Medicare and Medicaid, for example, each physician and pharmacist that participates in the program must sign a provider agreement with his or her state. Although there are variations in the agreements among the states, the agreement typically requires the prospective Medicare and Medicaid providers to agree that they will comply with all legal requirements, which include the AKS. In a number of states, the Medicare and Medicaid claim form itself contains a certification by the provider that the provider has complied with all aspects of the Medicare or Medicaid program, including compliance with federal laws.

63. Moreover, health care providers are acutely aware that compliance with the AKS is a condition of participation and a condition of payment. Pursuant to provider agreements, claims forms, or other documents, health care providers who participate in a federal health care program generally must expressly undertake to comply with the AKS, and thereafter certify (either impliedly or expressly) that they have complied with the applicable federal rules and regulations, including the AKS.

64. Any party convicted under the AKS must be excluded (*i.e.*, not allowed to bill for services rendered) from federal health care programs for a term of at least five years. 42 U.S.C. §1320a-7(a)(1). Even without a conviction, if the Secretary of HHS finds administratively that a provider has violated the statute, the Secretary may exclude that provider from the federal health

care programs for a discretionary period (in which event the Secretary must direct the relevant state agency or agencies to exclude that provider from the state health program) and may consider imposing administrative civil sanctions of $50,000 per kickback violation. 42 U.S.C. § 1320a-7a(a).

65. The enactment of these various provisions and amendments demonstrates Congress' commitment to the fundamental principle that federal health care programs will not tolerate the payment of kickbacks. Thus, compliance with the AKS is a prerequisite to a provider's right to receive or retain reimbursement payments from Medicaid and other federal health care programs. Reimbursement is also prohibited by the general legal principle that providers who are corrupt or unethical or violate the integrity of a Government program involving Government funds are not entitled to payment from the public for the resulting claims.

G. VIOLATION OF THE AKS IS GROUNDS FOR LIABILITY UNDER THE FCA

66. Violation of the AKS is expressly defined to constitute grounds for liability under the federal False Claims Act ("FCA"). 42 U.S.C. § 1320a-7(b)(g), as amended by the Affordable Healthcare for America Act (eff. March 23, 2010). Even prior to this express statement by Congress, the courts had interpreted an AKS violation as a proper predicate for FCA liability on the grounds that: 1) health care providers expressly undertake to comply with the AKS as a condition of payment, and thereafter certify (expressly and/or impliedly) that they have complied with the AKS as a condition of payment, thereby supporting liability for making false certifications (express and/or implied); and/or 2) violations of the AKS "taint" the claims submitted to the Government and render the claims "factually false" and ineligible for payment because they violate a condition of payment.[15]

[15] *See, e.g., U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235 (3d Cir. 2004).

67. With regard to the certification theory of FCA liability, in order to bill Medicare or Medicaid, health care providers must sign and submit to CMS various Provider Applications, Provider Agreements, and Claim Forms that include certifications of compliance with applicable laws – including the AKS.

68. Although the Medicaid Provider Application varies from state to state, the provider typically affirms and undertakes compliance with all applicable state and federal laws. In the standard Medicare Provider Agreement, the provider affirms and undertakes compliance as follows:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]. The Medicare laws, regulations, and program instructions are available through the [Medicare] contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to the federal Anti-Kickback statute and the Stark law), and on the [provider's] compliance with all applicable conditions of participation in Medicare.[16]

69. Even where the provider Application and Provider Agreement are construed as an undertaking of future compliance rather than an ongoing express certification of compliance, that undertaking is sufficient to render the ensuing claims for payment an implied certification of compliance with the stated conditions of payment.

70. In addition, the standardized Claim Form used for Medicare, CHAMPUS, and Medicaid, requires the provider to expressly affirm, respectively:

> SIGNATURE OF PHYSICIAN OR SUPPLIER (MEDICARE, CHAMPUS, …)
> * * *
> NOTICE: Any one [sic] who misrepresents or falsifies essential information to receive payment from federal funds requested by this form may upon conviction be subject to fine and imprisonment under applicable federal laws.

[16] Form CMS-855A (for institutional providers); Form CMS-855I (for physicians and non-physician practitioners; Form 855-S (for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Suppliers).

> MEDICAID PAYMENTS (PROVIDER CERTIFICATION)
> * * *
> NOTICE: This is to certify that the foregoing information is true, accurate and complete. I understand that payment and satisfaction of this claim will be from federal and state funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable federal or state laws.[17]

In other words, the provider expressly certifies that they are entitled to receive payment.

71. In the present case, all of the Health Care Providers who submitted claims for payment to Medicare and/or Medicaid would have signed the requisite provider Applications, Provider Agreements and Claim Forms, thereby supporting FCA liability for making false implied and/or express certifications of compliance with the AKS condition of payment.

72. In sum, either pursuant to physician agreements, claims forms, or other appropriate manner, health care providers who participate in a federal or state health care program generally must certify that they have complied with the applicable federal rules and regulations, including the AKS and its state analogues.

VI. J&J'S FRAUDULENT SCHEME TO INDUCE SALES OF ITS DRUG PRODUCTS

A. J&J KICKBACKS TO INDUCE PRESCRIBING

73. At its core, the Remicade/Simponi Aria kickback scheme consisted of a basic, and unlawful, quid pro quo between J&J and the Health Care Providers. J&J offered the Health Care Providers the opportunity to earn tens or hundreds of thousands of dollars in "performance rebates" and other monies by moving business for J&J. In exchange, the recipient Health Care Providers agreed to jettison their independent professional judgment, and, instead, become J&J's proxies in promoting the switching of Remicade prescriptions to Simponi Aria (which J&J

[17] Form CMS-1500 (08-05).

referred to as "conversion"), or to continue dispensing Remicade instead of competitor drugs, which were often cheaper Remicade biosimilar drugs and/or other cheaper, more effective drugs.

74. The crux of J&J's illicit scheme has been the payment of what it knew were illegal kickbacks to the Health Care Providers in exchange for their agreement (a) to keep purchasing and dispensing Remicade instead of cheaper biosimilars or other cheaper, more effective drugs, (b) to lock in Remicade and Simponi Aria purchases at or more than levels they were for the prior year, and (c) to switch patients from Remicade to Simponi Aria.

75. Those agreements, however, memorialized only one side of the bargain. Specifically, the rebate or discount contracts drafted by J&J showed only the financial terms of the bargains, including the rebate amounts (in terms of percentages of Remicade or Simponi Aria sales) and when the payments were due (if the Health Care Providers met certain market share or volume hurdles). By contrast, the promises or commitments that J&J extracted from the Health Care Providers – *i.e.*, to "convert" patients to Simponi Aria or to prevent the use of Remicade biosimilars – were left out of the contracts altogether, even though they were pivotal to J&J's decision to offer financial inducements.

76. J&J and the Health Care Providers earned hefty profits from their kickback scheme. For J&J, it was highly profitable to pay kickbacks in exchange for locking out biosimilar competitors while switching patients to Simponi Aria. For the Health Care Providers, they would profit handsomely from selling their influence and integrity, earning substantial kickbacks for doing J&J's bidding.

1. J&J's Remicade (Infliximab)

77. Infliximab is a tumor necrosis factor ("TNF")-inhibiting biologic drug used to treat a range of immune-mediated diseases, including Crohn's disease, ulcerative colitis ("UC"),

rheumatoid arthritis ("RA"), psoriatic arthritis ("PsA"), ankylosing spondylitis ("AK"), and plaque psoriasis ("PP").

78. As a biologic, infliximab is not synthesized in a laboratory, but rather derived from a living organism and is purified by a series of steps that includes measures to inactivate and remove viruses.

79. Infliximab is an infusion therapy, meaning it is administered intravenously. Thus, infliximab patients must (in most cases) visit clinics, hospitals, or other medical facilities to receive the therapy from the Health Care Providers. As a result, patients rarely purchase infliximab themselves at retail pharmacies. Instead, infusion centers, clinics, and hospitals purchase infliximab, and after administration, seek reimbursement from the patient's insurer or a government payer (*e.g.*, Medicare).

80. J&J introduced the first infliximab product in the United States in 1998, under the brand name Remicade.

81. Remicade's label contains a black box warning for "Serious Infections and Malignancy." The label also contains warnings for hepatotoxicity, heart failure, and cardiovascular and cerebrovascular reactions. The most common side effects of using Remicade include abnormal liver function, abnormally low blood pressure, anemia, hives, and acute respiratory infection of the nose, throat, or sinus.[18] Some patients taking Remicade have experienced high blood pressure, bronchitis, and higher susceptibility to infections.

82. Remicade is widely used: An estimated 475,000 patients in the U.S. receive at least one dose of Remicade annually. This fact, combined with the cost (approximately $4,000

[18] Available at https://www.webmd.com/drugs/2/drug-16554/remicade-intravenous/details/list-sideeffects

per infused dose at list price), makes administering Remicade a major expense item for Medicare and Medicaid.

83. J&J's list price increases for Remicade and other pricing actions have resulted in consistent increases in Remicade's ASP. J&J has increased the price of Remicade without experiencing a loss of sales to other therapies. Instead, Remicade sales have increased steadily since it was introduced. Indeed, J&J has been able to continue raising the price of Remicade notwithstanding the arrival of Remicade biosimilars.

84. For RA, the recommended dose of Remicade is 5 mg/kg. The initial treatment is followed by additional treatments at two and six weeks, followed by regular treatments every eight weeks. This means a patient would receive eight infusions of Remicade during their first year of treatment, and seven infusions every year thereafter.

85. One vial of Remicade 100mg costs approximately $1,100.[19] At 80kgs, an individual would need 4 vials per treatment, leading to a cost of approximately $4,400 per treatment. With 8 treatments during the first year of treatment, the total annual cost would be $35,200. For all subsequent years (with 7 treatments), the annual cost comes to $30,800.

86. Since 1998, J&J has made billions of dollars in profit on Remicade, including the following sales from 2008 through 2016[20]:

- 2016: $6.966 billion
- 2015: $6.561 billion
- 2014: $6.868 billion
- 2013: $6.673 billion
- 2012: $6.139 billion

[19] Available at https://www.goodrx.com/remicade?drug-name=remicade
[20] Available at http://fortune.com/2016/10/18/johnson-johnson-remicade/

- 2011: $5.492 billion
- 2010: $4.610 billion
- 2009: $4.304 billion
- 2008: $3.748 billion

2. J&J's Simponi Aria (Golimumab)

87. Golimumab is a human monoclonal antibody which is used as an immune-suppressive drug and marketed under the brand name Simponi and Simponi Aria.

88. Golimumab was developed by Janssen Biotech, Inc. (formerly Centocor Biotech, Inc.), which also markets the product in the United States.

89. On July 19, 2013, J&J's biologic Simponi Aria was approved by the FDA, in combination with methotrexate, as a 30-min intravenous infusion for the treatment of adult patients with moderate-to-severe active RA.[21] On October 20, 2017, the FDA approved Simponi Aria (golimumab) for the treatment of adults with active psoriatic arthritis or active ankylosing spondylitis.[22]

90. Simponi Aria's label contains a black box warning for "Serious Infections and Malignancy," such as "serious infections leading to hospitalization or death including tuberculosis, bacterial sepsis, invasive fungal, and other opportunistic infections."[23] The label also contains warnings for Hepatitis B Reactivation, heart failure, demyelinating disorders, and lupus-like syndrome. The most common side effects reported in patients taking Simponi Aria

[21] Available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2013/125433Orig1s000ltr.pdf
[22] Press Release, October 20, 2017, *Janssen Receives Two U.S. FDA Approvals For Simponi Aria® (Golimumab) For The Treatment Of Adults With Active Psoriatic Arthritis Or Active Ankylosing Spondylitis,* https://www.jnj.com/media-center/press-releases/janssen-receives-two-us-fda-approvals-for-simponi-aria-golimumab-for-the-treatment-of-adults-with-active-psoriatic-arthritis-or-active-ankylosing-spondylitis
[23] Simponi Aria Package Insert, http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/SIMPONI-ARIA-pi.pdf

include upper respiratory infection, abnormal liver function, decreased blood cells that fight infection, viral infections, bronchitis, high blood pressure, and rash.[24]

91. Simponi Aria costs between $1,000 and $3,000 per month, with many pharmacies charging approximately $1,800 to $2,000 per vial (4ml) of Simponi Aria 50mg/4ml. The prescribing information recommends a dosage of 2mg/kg of the patient's weight. As an example, a 180lb person weighs approximately 80 kg. Thus, he/she would receive approximately 160 mg of Simponi Aria, or 3 vials. Assuming a cost of $2,000 per 50mg vial, the cost for one treatment would be $6,000. Since the treatment is good for 2 months, the monthly cost would be $3,000, or $36,000 annually. During the first year of treatment, the patient receives an extra dose (at 0 weeks, 4 weeks, then every 8 weeks), which brings the cost of treatment for the first year to $42,000, then $36,000 per year after that.[25]

92. Since Simponi Aria came to market in 2013, J&J has made billions of dollars in profit from Simponi Aria and Simponi (which is J&J's subcutaneously administered form of golimumab), including annual sales from 2013 through 2017:

- 2017: $1.8 billion ($954 million in the US)
- 2016: $1.745 billion
- 2015: $1.328 billion
- 2014: $1.187 billion
- 2013: $932 million

93. Other competing drugs used to treat PsA, AS, and/or RA include Humira (AbbVie), Cimzia (UCB, Inc.), Enbrel (J&J & Pfizer), Orencia (Bristol-Myers Squibb), Kineret

[24] Available at https://www.simponiaria.com/what-is-simponi-aria/side-effects-and-safety/
[25] Simponi Aria Package Insert

(Orphan Biovitrum AB), Remicade (Janssen), Rituxan (Genentech & Biogen Idec.), and Actemra (Genentech).

94. There is no biosimilar available for Simponi Aria.

B. REMICADE BIOSIMILARS

1. Inflectra – Pfizer Remicade Biosimilar

95. After rigorous scientific review, the FDA approved the Remicade biosimilar Inflectra (infliximab-abda), developed by Pfizer, on April 5, 2016. In the FDA news release announcing its approval of Inflectra, the director of FDA's Center for Drug Evaluation and Research reiterated that approval as a biosimilar reflects a determination of "no clinically meaningful differences" from the originator and stated that "[p]atients and the healthcare community can be confident that biosimilar products are high quality and meet the agency's rigorous scientific standards."[26]

96. On August 17, 2016, J&J's patent covering the infliximab antibody was ruled invalid by the United States District Court for the District of Massachusetts, a ruling which confirmed that J&J had no valid right to exclude Inflectra (or other potential biosimilar entrants), holding that the antibodies covered by J&J's Remicade patent had been disclosed and claimed in an earlier patent.[27] Just a few months after the district court ruling, the U.S. Patent and Trademark Office issued a final decision in a re-examination of the same patent, holding that the patent was invalid.[28]

97. After overcoming these hurdles, and after a 180-day notice period required by the BPCIA, Pfizer began to market the first Remicade biosimilar, Inflectra, in November 2016.

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[26] *See* U.S. Food & Drug Administration, *FDA Approves Inflectra, A Biosimilar to Remicade* (Apr. 5, 2016), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm494227.htm.
[27] Janelle Lawrence, *J&J Remicade Patent Found Invalid in U.S. Victory for Pfizer*, Bloomberg (Aug. 17, 2016), https://www.bloomberg.com/news/articles/2016-08-17/j-j-patent-on-remicade-expiring-in-2018- invalid-judge-rules
[28] *Id.*

98. Inflectra is approved for all the same indications as Remicade, except pediatric ulcerative colitis, as to which J&J continues to enjoy an FDA-granted period of exclusivity because of the indication's status as an "orphan" indication (established on proof that the number of people affected by the disease or condition for which the drug is to be developed is fewer than 200,000 persons), which is scheduled to end in 2018.

99. Pfizer introduced Inflectra with a list price 15 percent lower than Remicade's, and, in negotiations with insurers and physicians, offered substantial additional pricing concessions in the form of discounts and/or rebates that in some instances were more than 40 percent below Inflectra's list price.

2. Renflexis – Merck/Samsung Bioepis Remicade Biosimilar

100. The FDA approved the second Remicade biosimilar, Renflexis, on April 24, 2017.[29] Renflexis (infliximab-abda) was developed by Merck and Samsung Bioepis, a joint venture of Samsung and Biogen. As with Inflectra, Renflexis is approved for all the same indications as Remicade, except pediatric ulcerative colitis.

101. On July 24, 2017, Merck & Co. announced it had launched its Renflexis in the U.S. at a list price of $753.39—which is a 35% discount to the current list price of Remicade. The list price reflects wholesaler acquisition cost, which does not include other discounts that may be paid on the products.

C. GOVERNMENT PROGRAM COVERAGE FOR REMICADE AND SIMPONI ARIA

102. Most patients in the U.S. who are prescribed Remicade or Simponi Aria have some form of insurance coverage or qualify for patient assistance. The sources of insurance coverage are (a) private insurance, accounting for about 60 percent of patients nationally, and (b)

[29] *FDA approves biosimilar infliximab Renflexis*, GaBi (May 5, 2017), http://www.gabionline.net/Biosimilars/News/FDA-approves-biosimilar-infliximab-Renflexis.

Government Programs (principally Medicare and Medicaid), accounting for the remaining 40 percent. Medicare and Medicaid coverage and reimbursement are therefore key to the adoption of the product by patients and health care providers alike. Not surprisingly, if a product as expensive as Remicade is not widely reimbursed by Medicare and Medicaid, it will not be significantly utilized.

103. Because Remicade and Simponi Aria are not dispensed in a retail pharmacy but rather administered intravenously in an infusion clinic or other institutional setting, they generally are not included under the "pharmacy benefit" of most health plans – *e.g.*, Medicare Part D – but are instead covered under the medical benefit, *e.g.*, Medicare Part B.

104. In the pharmacy benefit setting, physicians prescribe a drug and the patient procures the medication him or herself at the pharmacy, paying for it with a combination of insurance coverage (either private or government-sponsored) and out-of-pocket payment (usually, a co-pay). In the pharmacy benefit context, neither the prescribing physician nor the institution with which the physician is affiliated bears financial risk with respect to the drug selected – i.e., the drug is not purchased and stocked in advance by physicians at their own cost. The pharmacy buys the drug, dispenses it, and is reimbursed.

105. In contrast, "medical benefit" products such as Remicade and Simponi Aria are administered at an infusion clinic or other health care physician site, and the physician first purchases the drug product for use in the infusion treatment of patients, and then later seeks reimbursement for the drug from a third-party payer (a practice commonly referred to as "buy and bill"). When a treatment is administered, the physician must secure payment for the service, including the cost of the product dispensed (which the physician had to pay up front with its own

funds). In this context, the physician has a strong interest in utilizing drugs that are widely covered by insurance, particularly by Medicare and Medicaid.

106. If a drug product is not widely covered by Medicare and Medicaid, such that there is a risk that coverage might be denied, and physicians thus would be burdened with a potential financial loss for what they paid for the product, physicians are much less likely to purchase that product—a response that is in line with the physicians' economic interests (to be reimbursed).

107. Many of the facilities administering infusion services of the type at issue here are physician-owned. Thus, the physicians themselves have both prescribing authority and a strong financial incentive to avoid products that are not widely covered.

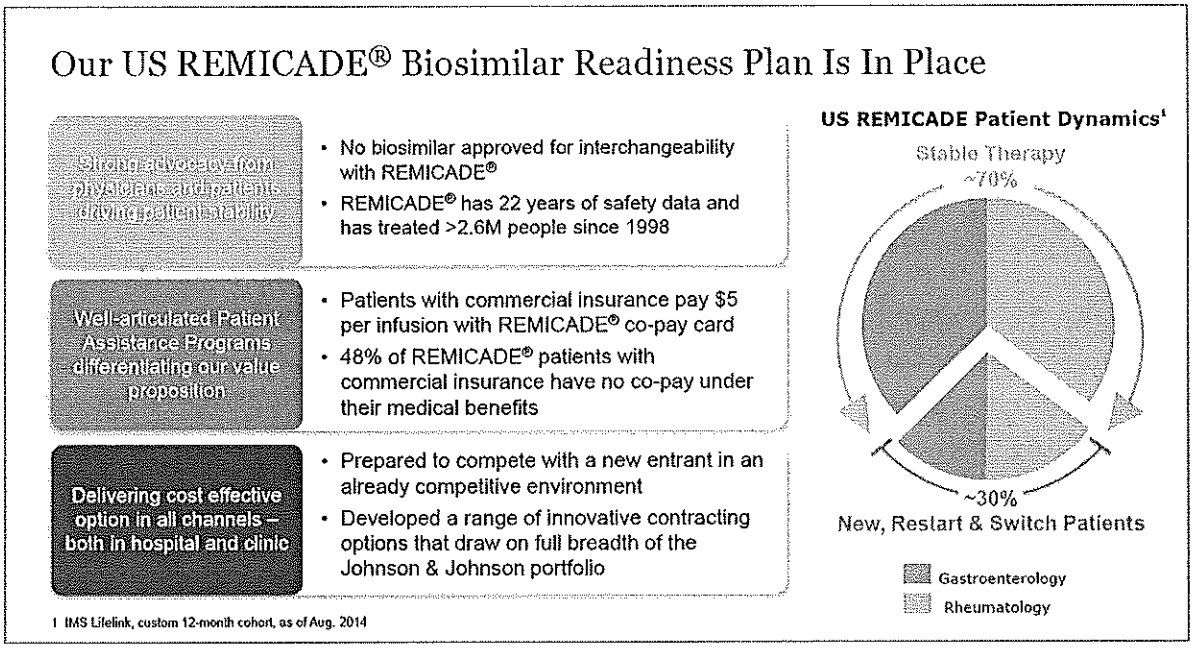
D. J&J'S "BIOSIMILAR READINESS PLAN"

108. As alleged above, physicians (hospitals, clinics, etc.) actually purchase infliximab for use with their infusion services for patients. Providers do not want to risk being unable to secure reimbursement for any drug used to treat a patient after having already paid for the product. Because it can be costly to monitor coverage status and implement procedures to match product use to a patient's coverage, gaps in reimbursement policies give "buy and bill" physician accounts reasons to stock only products with the greatest likelihood of universal (or near-universal) coverage.

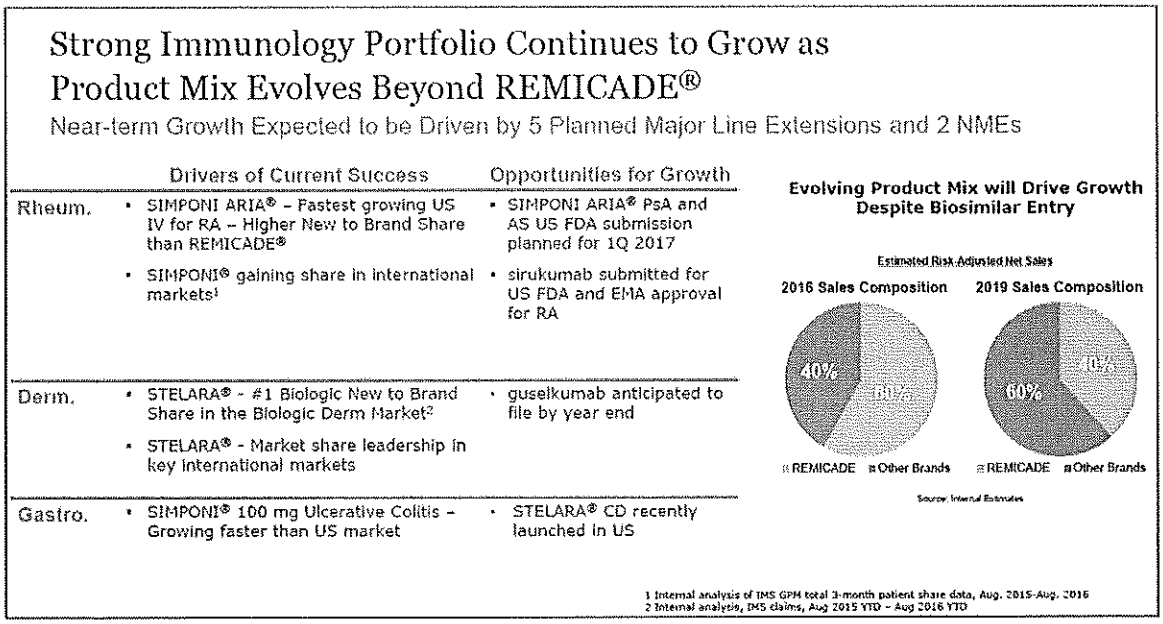
109. Not content with its nearly two full decades of exclusivity with Remicade, and the billions of dollars of profits that such exclusivity enabled, J&J hatched a scheme to ensure that Remicade biosimilars would never become viable competitors—a scheme embodied, at least in part, in its "Biosimilar Readiness Plan." J&J revealed the existence of the plan, and at least some specifics thereof, during a 2016 investor call and presentation.[30]

[30] Johnson & Johnson, Q3 2016 Results Earnings Call Transcript (Oct. 14, 2016), available at https://seekingalpha.com/search/transcripts?term=johnson+%26+Johnson+biosimilar.

110. During the call by Joaquin Duato, Executive Vice President, Worldwide Chairman, Pharmaceuticals for J&J, presented the following slide summarizing the plan, including the statement that J&J had "[d]eveloped a range of innovative contracting options that draw on full breadth of the Johnson & Johnson portfolio":



111. Duato also told investors that J&J had developed other immunology products which would "counter" Remicade biosimilar entry. These products, including Simponi Aria, would drive growth "beyond Remicade":



112. The "full breadth of [J&J's] portfolio" includes J&J drugs Simponi (used for rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and ulcerative colitis), Simponi Aria (used for rheumatoid arthritis), and Stelara (used for plaque psoriasis, psoriatic arthritis, and Crohn's disease). These products are widely used, with Simponi/Simponi Aria generating for J&J approximately $1.7 billion in 2016 and Stelara generating approximately $3.2 billion in 2016.

113. J&J has been marketing Remicade using what it calls the "Finely Tuned" program,[31] which encouraged patients to stay on Remicade if a biosimilar is offered.[32] In this marketing campaign (website was last updated in 2017), Janssen argues that "no infliximab biosimilar has yet proven [that] it will work the same as Remicade for anyone who takes it" and that "no infliximab biosimilar has yet proven [that] switching or alternating back and forth

[31] https://www.finelytuned.com/
[32] http://blog.dtwresearch.com/?tag=simponi-aria

between the interchangeable biologic and Remicade would not cause any changes in safety or how well the treatment works."[33]

114. In order to counter the impact of the Biosimilar Readiness Plan on the slow sales of its drug Inflectra, Pfizer filed suit on September 19, 2017 in the Eastern District of Pennsylvania, alleging that J&J and its subsidiary Janssen Biotech Inc. had been holding onto an anticompetitive Remicade monopoly through a multifaceted anti-competitive campaign.[34] The Pfizer suit alleged that "[t]he core features of the plan are exclusionary contracts that foreclose Pfizer's access to an overwhelming share of consumers, coupled with anti-competitive bundling and coercive rebate policies designed to block both insurers from reimbursing, and hospitals and clinics from purchasing, Inflectra or other biosimilars of Remicade despite their lower pricing."[35]

115. In response to the antitrust lawsuit brought by Pfizer contending that J&J had been engaged in anti-competitive exclusionary conduct with regard to Remicade, the Company explained its "aggressive discounts" on Remicade: "Biosimilars are not generics, and should not be considered as such. In this highly competitive class, we are providing aggressive discounts which we believe in turn will drive down costs for the healthcare system and patients."[36]

116. Even though J&J's Biosimilar Readiness Plan has helped to preserve Remicade market share, the steep discounts the Company had been offering began to eat into revenues. During a January 22, 2018 earnings call, J&J explained the nearly 9 percent drop in U.S. Remicade revenues was associated with price declines rather than a decline in sales: "REMICADE in the U.S. declined more than 8%, as we continued to compete in the phase of

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[33] https://www.finelytuned.com/biosimilars-and-biologics.html

[34] Dani Kass, *J&J Blocking Remicade Biosimilar Sales, Pfizer Says,* Law360 (Sept. 20, 2017), available at https://www.law360.com/articles/965937

[35] *Id.*

[36] Ed Silverman, *J&J tries to bolster Remicade use, but raises concern about healthcare costs*, Stat+ (Nov. 20, 2017)
available at https://www.statnews.com/pharmalot/2017/11/20/johnson-and-johnson-remicade-advisors/

biosimilar entries. While this is more of a decline than the modest levels of erosion we experienced during the first three quarters of 2017, demand was relatively stable and the erosion was primarily driven by negative price. REMICADE U.S. export and international businesses declined as erosion from biosimilar competition persists in key markets."[37] The negative price reference is in part explained by the substantial rebates alleged herein: "So, all of the change that you saw in the quarter of about 9% down was associated with price declines."[38]

117. J&J's conduct has not gone entirely unnoticed. For example, an analyst at a securities firm (Bernstein Research) summarized key aspects of J&J's scheme, observing that J&J has: (a) "negotiated with [insurers]" and set up "exclusive contracts . . . in nearly half the market," thereby making physicians unwilling to purchase Remicade biosimilars; (b) "offered up deeper discounts to large independent infusion centers [*i.e.*, major physicians], which are more economically sensitive"; and (c) "bundled several drugs and medical devices [together] for larger hospitals."[39] The analyst also noted that a key to J&J's strategy was the "long 'tail' of [patients] remaining on the brand,"[40] which gives J&J leverage to extract commitments from insurers not to cover Remicade biosimilars.

118. Another industry observer, commenting on the Bernstein survey, noted that J&J has had yet another advantage—an ability and willingness to bundle its own medicines with Remicade as part of a package deal. By offering discounts and rebates for Remicade and several

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[37] Johnson & Johnson, Q4 Results Earnings Call Transcript (Jan. 22, 2017), available at https://seekingalpha.com/article/4139545-johnson-and-johnsons-jnj-ceo-alex-gorsky-q4-2017-results-earnings-call-transcript?page=22.

[38] *Id.*

[39] Aaron Gal, *Biosimilars: So, Why Has Remicade Biosimilar Not Gotten Much Traction in the U.S.*, Bernstein Research, at 1 (July 20, 2017).

[40] *Id.*

of its drugs, this observer opined that J&J can secure contracts and crowd out rivals. And discounts were also attractive to physicians who run their own infusion centers.[41]

E. J&J'S UNLAWFUL PAYMENTS TO THE HEALTH CARE PROVIDERS VIOLATED THE AKS

119. As a clandestine part of its Biosimilar Readiness Plan, J&J has used confidential kickbacks in its contracts with the Health Care Providers to hold Remicade market share while it then implemented an illegal scheme to induce conversion of prescriptions to Simponi Aria (which is not subject to immediate loss of patent protection and the attendant biosimilar competition).

120. For physicians, J&J calls this discount program its Contract Purchase Program ("CPP"), a Remicade discount program that has been in place for at least since October 1, 2010. J&J had similar agreements in place for infusion centers and GPOs. Collectively herein these are referred to as the "Agreements." Only as of January 2018 has J&J adapted the Agreements into the centerpiece of its clandestine kickback scheme.

121. The initial 2010 Agreements simply provided what were legitimate pricing concessions to Health Care Providers over and above any discounts received as a result of purchasing Remicade and Simponi Aria from specialty pharmacies.

122. The initial October 1, 2010 Agreements included only general boilerplate language regarding the obligation to disclose "in any cost reports or claims for reimbursement submitted to Medicare, Medicaid or certain other health care programs, the cost (including, but not limited to, Price Concessions or any other price reductions) of any Product purchased under this agreement . . ..":

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[41] Ed Silverman, *J&J Now Has Two Competitors for A Pricey Blockbuster. Will That Finally Drive Down Prices?* Stat News (July 25, 2017), available at https://www.statnews.com/pharmalot/2017/07/25/mercksamsung-biosimilar-pfizer-johnson/.

2.15 Pricing Disclosure. (a) The Customer acknowledges that, by law, it (and any Participating Physician if the Customer is a HCP Entity) is required to disclose, in any cost reports or claims for reimbursement submitted to Medicare, Medicaid, or certain other health care programs, the cost (including, but not limited to, Price Concessions or any other price reductions) of any Product purchased under this agreement and, on request, provide to the U.S. Department of Health and Human Services and any state agencies, any invoices, coupons, statements, and other documentation reflecting such costs for Products. The Customer may receive subsequent documentation under some programs reflecting adjustments or allocations to the Price Concessions available hereunder.

123. The initial Agreements have been amended over time as J&J rolled out its Biosimilar Readiness Plan. Yet, none of the amendments mentions anything about potential violations of the AKS or the obligation to disclose any agreement not to substitute a cheaper biosimilar or to engage in product conversion programs.

124. Even though it is silent about any AKS aspects of the deals offered, the fifth amendment to the CPP, for example, beginning in Q1 2018 for physicians and Q4 2017, in addition to its "Simponi Aria ASP-Like Price," offered Health Care Provers significant bribes, in exchange for their agreement (a) to continue purchasing and prescribing Remicade instead of cheaper Remicade biosimilars, (b) to lock in Remicade and Simponi Aria purchase levels where they had been a year prior, and (c) to initiate a conversion program where they were incentivized to switch from Remicade to Simponi Aria:

- **Tiered "Performance Based Rebates" as Part of its Biosimilar Readiness Program to Retain Remicade Market Share and Fend Off Remicade Biosimilars.** Under the new Agreements' terms, Health Care Providers are offered what are characterized as "Performance Based Rebates" or "price concessions" (also euphemistically called "pricing stability"):

1. 60-119 vials **1% rebate**
2. 120-179 vials **2% rebate**
3. 180-239 vials **3% rebate**
4. 240-299 vials **4% rebate**

5. 300-499 vials **5% rebate**
6. 500-999 vials **6% rebate**
7. 1000+ vials **8% rebates**

On top of these 7-tiered rebates, the GPO Defendants would also receive an additional 1% rebate on all their purchases.

- **Bonuses For Locking in Remicade and Simponi Aria Purchases at Prior Year Levels.** For quarters commencing April 1, 2018 and July 1, 2018, J&J also began offering an additional $5 per vial discount on purchases of Remicade if "Total Combined Product Units" purchased equal or exceed ninety-five percent (95%) of its "Total Remicade Product Units" purchased for same quarter of the prior calendar year. The "Total Combined Product Units" included its bundling of purchases for both Remicade and Simponi Aria. The monies were available for all Remicade and Simponi Aria purchases during the following two quarters.
- **2:1 Conversion Bonuses in Favor of Simponi Aria as a Reward for Interchange.** In addition, the Agreements added a 2:1 bonus for "Total Simponi Aria Converted Product Units," which effectively doubled the $5 bonus for converting Remicade prescriptions to Simponi Aria. Here is the language from Amendment 5 of the CPP Agreement:

> "Total SIMPONI ARIA® Converted Product Units" means the total number of SIMPONI ARIA® Product Units (as defined in Schedule A-2) multiplied by two (2).

The Agreements' weighting meant that the Health Care Providers were rewarded with double the amount of bonus for converting scripts from Remicade to Simponi Aria. These bonuses have been significant drivers of Health Care Provider purchases. Coupled with the substantial performance rebates, the

Agreements structure the kickbacks to reward Health Care Providers who kept Remicade/Simponi Aria purchase levels at 95% or above where they were before Remicade biosimilars came to market.

125. This package of illegal incentives came at a time when the Company faced stiff competition from Remicade biosimilars. By requiring that the Health Care Providers must maintain purchases of at least 95% of the weighted volume of Remicade purchases for the same period during the prior year (while rewarding 2:1 for switches to Simponi Aria), these kickbacks (a) effectively "lock in" purchase levels at the pre-Remicade biosimilar quantities; (b) rewards the refusal to prescribe Remicade biosimilars; and (c) bribes the Health Care Providers to convert Remicade prescriptions to Simponi Aria.

126. J&J has instructed sales representatives on how to present these incentives. Even though they were told they could not "sell on spread," representatives were still trained to show physicians how they could maximize their monies under the Agreements, using the Company's iPad "Performance Estimator" to demonstrate how the Health Care Providers could move to higher tiers and get higher rebates on Remicade and Simponi Aria. For example, for Health Care Providers hitting the second tier for Simponi Aria, they would not only receive double the performance rebate, they would receive four times as much of the conversion bonus as they would have received if they had purchased Remicade. J&J managers trained representatives to use the "Performance Estimator" to explain the kickbacks to Health Care Providers, who were told that if they use Remicade and Simponi Aria for all of their patients, they could reach higher tiers of the CPP. That would give the Health Care Providers monies back on all of their total purchases of Simponi Aria and on Remicade in addition to the margin on reimbursement from Medicare, Medicaid and other Government Programs.

127. If Health Care Providers decline to use the Remicade/Simponi Aria switch, they are shown how they would sacrifice significant monies. In this manner, J&J has been able to induce Health Care Providers to choose Remicade/Simponi Aria, even if it was not always the best clinical choice for the patient or the cheapest alternative for Medicare, Medicaid, or other Government Programs.

128. Health Care Providers were also implicitly (if not explicitly) made aware they would be punished financially for buying drugs from a competitor. Representatives were trained to show Health Care Providers how the extra competing drug that the doctor had purchased would result in a lower tier on the contract with J&J.

129. J&J representatives were trained to use the dollar amount of the competing drugs in the "Performance Estimator" to illustrate how much money Health Care Providers were leaving on the table by continuing to use the competing drug, with no regard for which drug was the better clinical choice. In this manner J&J was able to stabilize its Remicade market share in the face of biosimilar competition and begin to convert patients to Simponi Aria, which faces no biosimilar competition.

F. J&J's Performance Rebates and Payments to the Health Care Providers Conditioned on Their Conversion Activities (or to Oppose Remicade Biosimilar Substitution) Are Not "Discounts" Under 42 U.S.C. § 1320a-7b(b)(3)

130. By law, the AKS does not impose liability for remuneration that is "a discount or other reduction in price ... if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a federal health care program." 42 U.S.C. § 1320a-7b(b)(3).

131. Regulations interpreting the AKS provide an independent safe harbor for discounts offered to charge-based providers if: (1) they are "made at the time of the sale," and

"fixed and disclosed in writing . . . at the time of the initial sale" and (2) the provider furnishes, "upon request by the Secretary or a state agency," documentation both of the discount and that provider's awareness of its obligation to report it. 42 C.F.R. § 1001.952(h)(1)(iii).[42]

132. If a rebate is conditioned on more than a simple purchase, it is not a mere "discount," but rather a form of remuneration whose legitimacy must be evaluated under the AKS separate and apart from the statutory discount exception or regulatory discount safe harbor. In other words, if a price reduction is conditioned on more than the purchase of a product, then it is not a mere discount and it is irrelevant whether that price reduction was "properly disclosed."

133. If J&J and the Health Care Providers had maintained their original 2010 pricing structure that offered escalating discounts in return for increased sales of Remicade and Simponi Aria, and J&J then independently (not pursuant to the Agreements with the Health Care Providers) had relied on separate sales tactics to achieve the increased sales, then perhaps such arrangements would qualify as "discounts" and therefore would not violate the AKS, but only if the monies were properly disclosed and appropriately reflected in the costs claimed or charges made by the provider.

134. But J&J's enhanced 2018 monies, in contrast, were made as an integral part of the sales representative's core sales details, tying the offer of monies being paid by J&J to the Health Care Providers' specific agreement not to switch to biosimilars and/or to convert from Remicade to Simponi Aria. These were thus not mere price reductions separate and apart from J&J's promotional activity. As such, the payments were not true price discounts, but rather were

[42] Congress, directing the Secretary of Health and Human Services to promulgate regulations "specifying payment practices that shall not be treated as a criminal offense" under the AKS, provided that "[a]ny practices specified in regulations . . . shall be in addition" to those exempted by the AKS itself. Pub. L. No. 100-93, § 14(a), 101 Stat. 680, 697 (1987). See also 64 Fed. Reg. 63,518, 63,528 (Nov. 19, 1999) ("In sum, the regulatory [discount] safe harbor both incorporates and enlarges upon the statutory [discount] exception.")

remuneration that J&J offered and paid as part of its illegal inducement of Health Care Providers to recommend its products Remicade and Simponi Aria instead of cheaper alternative drugs.

135. J&J's performance rebate payments were, in the language of the AKS, "remuneration . . . to induce [the Health Care Providers] to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering" defendants' drugs, "for which payment [was] made in whole or in part under a federal health care program." 42 U.S.C. § 1320a-7b(b)(1). J&J's rebate payments to the Health Care Providers were contingent on the Health Care Providers taking specific steps to increase utilization of those drugs.

136. Likewise, J&J's use of the term "performance rebates" does not automatically cloak those payments with the protection of the AKS's exception for discounts. As the HHS-OIG cautioned in its Compliance Program Guidance for Pharmaceutical Manufacturers, "any remuneration from a manufacturer to a purchaser, however characterized, should be carefully scrutinized." 68 Fed. Reg. at 23,735. J&J's payments to the Health Care Providers do not survive such careful scrutiny.

137. Nor do the J&J attempted disclosures satisfy the requirements of the AKS regulatory safe harbor. As the HHS has clarified through rulemaking, this exemption requires the discount, or terms of the rebate, to "be fixed and disclosed in writing to the buyer at the time of the initial sale of the good or service." 42 C.F.R. § 1001.952(h)(1)(iii) (2016). The regulatory safe harbor likewise requires the buyer provide, "upon request by the Secretary or a state agency," an "invoice, coupon or statement" from the seller that "fully and accurately" reports such discount. *Id.* §§ 1001.952(h)(1)(iii)(B), (h)(2)(iii)(B).

138. Along with its performance rebate payments, J&J includes the following attempted disclosure to the Health Care Providers:

Re: SIMPONI ARIA® Rebate calculation under the Contract Purchase Program Agreement between Johnson & Johnson Health Care Systems Inc. ("Company") and Customer effective October 1, 2010 ("CPP Agreement")

Dear Customer:

This is to inform you that a payment in the amount of $1,962.70 was calculated under the above referenced CPP Agreement during the period of January 1, 2018 through March 31, 2018. This payment is being sent separately via EFT or Check in accordance with your previous instructions. The attached customer payment report provides detailed information regarding the payment.

These reports include information pertaining to the following: Price concessions on products purchased under the CPP Agreement if certain conditions are met. Company is providing payment of these price concessions as permitted by the "discount safe harbor" to the federal anti-kickback statute under 42 C.F.R. §1001.952(h).

Please be advised that all or part of this payment may be considered a discount, which Customer (or your physicians, as applicable), may have an obligation to reflect in any cost report or claim for reimbursement filed with Medicare/Medicaid or other third-party payer.

If you have any questions regarding this payment, please do not hesitate to contact the Johnson & Johnson Health Care Systems Inc. contract hotline at (866) 317-2764, Monday through Friday, from 8:30 AM to 5:00 PM E.T.

Sincerely,

JOHNSON & JOHNSON HEALTH CARE SYSTEMS INC.

139. Because the remuneration is not the mere reduction in price of Remicade and Simponi Aria, but illegal kickbacks designed and intended to induce the Health Care Provider to purchase (and prescribe) Remicade and Simponi Aria, the mere disclosure that this payment "may be considered a discount" was woefully sufficient to qualify under the regulatory discount safe harbor.

140. Here, there was no proper disclosure by J&J because neither the contracts nor the letters with performance payments disclosed that J&J's largesse was conditioned on the Health Care Providers not only purchasing its products, but also their complicity in a scheme (a) to refuse to substitute Remicade biosimilars, (b) to lock in Remicade/Simponi Aria purchase levels, and (c) to switch from Remicade to Simponi Aria.

141. J&J's disclosures thus fail to pass muster under the statutory or regulatory discount safe harbors. What makes J&J's activity illegal is not the label that attached to the form of the transaction. Instead, J&J's intent behind the transaction and its requisite state of mind underlying the illegal act are more significant than the label.

142. Not only that, but in Relator's experience no Health Care Providers ever notified the Government of the scheme.

143. The collusive quality of the J&J arrangements with the Health Care Providers alleged herein fundamentally distorts the transparency of price competition in the healthcare market that Congress sought to promote with the discount safe harbor.

144. J&J's scheme was a huge success. When, effective January 15, 2018, J&J amended its Agreements with the Health Care Providers to increase the monies they would receive if they blocked Remicade biosimilars, locked in purchase levels, and met Simponi Aria conversion targets, the Health Care Providers refused to prescribe cheaper biosimilars and promptly converted numerous Remicade prescriptions to Simponi Aria, increasing sales dramatically.

145. The J&J monies, conditioned on the Health Care Providers' illegal refusal to prescribe biosimilars and agreement to switch from Remicade to Simponi Aria, are therefore not 'discounts' within the meaning of the discount exception at 42 U.S.C. § 1320a-7b(b)(3) and its interpreting regulations. Remuneration that is contingent on the recipient taking affirmative steps to generate additional business for the seller does not foster price competition that inures to the benefits of the health care system.

G. THE DEFENDANTS CAUSED FALSE CLAIMS TO BE SUBMITTED TO THE GOVERNMENT

146. As J&J and the Health Care Providers profited from their kickback scheme through, respectively, escalating levels of Remicade and Simponi Aria sales and ongoing flows of kickback payments, Medicare, Medicaid and other Government Programs were made to bear the financial cost of this corrupt scheme.

147. That the Health Care Providers submitted false claims for reimbursement for Remicade and Simponi Aria to Medicare, to state Medicaid programs and to other Government Programs was a foreseeable factor in the Government's losses, and a consequence of the Defendants' fraudulent schemes.

148. Further, in seeking reimbursement from Medicare, Medicaid, and other Government Programs, neither these Health Care Providers nor J&J disclosed their quid pro quo arrangements. The Remicade and Simponi Aria kickback scheme resulted in the submission of tens of thousands of false claims to Medicare, Medicaid, and other Government Programs.

149. Those false claims, in turn, caused Medicare, Medicaid, and other Government Programs to disburse tens of millions of dollars in reimbursements that should not have been paid. Thus, J&J and the Health Care Providers have, through their kickback scheme, knowingly caused tens of millions of dollars in losses to those federal and state programs.

150. Accordingly, kickback-tainted claims for reimbursement are false claims within the meaning of the federal FCA and state analogues.

VII. J&J VIOLATED ITS CIA

151. Since 2014, J&J has been under a CIA arising out of allegations that J&J engaged in illegal pricing and promotion of Risperdal, Invega, and Natrecor. Under this CIA, J&J agreed to undertake obligations designed to promote compliance with federal health care program and FDA requirements.[43] The J&J CIA is an express contract between J&J, HHS, and the United States Government.

152. In order to execute its unlawful conduct, J&J needed to conceal its illegal conduct from Government oversight, particularly in light of the fact that it was operating under a CIA.

[43] *See* J&J CIA, *available at* https://oig.hhs.gov/fraud/cia/agreements/johnson_johnson_10312013.pdf.

153. Accordingly, J&J engaged in a deliberate plan to knowingly submit false reports to the OIG—as required per the terms of the CIA—that either materially misrepresented the facts concerning its illegal conduct or concealed such conduct altogether. As such, J&J knowingly made, used, or caused to be made or used, false records or statements material to an obligation to pay or transmit money or property to the Government, or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government.

A. THE 2014 CIA ESTABLISHED J&J'S MONITORING AND REPORTING OBLIGATIONS

154. All of J&J's employees have been aware of the CIA, as the CIA required a written Code of Conduct be distributed to all Covered Persons, and each Covered Person was required to certify, in writing, that he or she had received, read, understood, and would abide by this Code of Conduct.[44] The Code of Conduct was to specify that all Covered Persons were expected to comply with the requirements of the CIA.[45] Per the CIA, a "Covered Person" included J&J's officers, directors, and United States-based employees.[46]

155. The CIA also contained an express contractual agreement that all J&J's employees "shall be expected to report to the J&J COO, or other appropriate individual(s) designated by J&J, suspected violations of any federal health care program requirements, FDA requirements, or of J&J's or any Pharmaceutical Affiliate's own Policies and Procedures."[47] The CIA further required J&J to notify the Government of any "reportable events," defined to include any "matter that a reasonable person would consider a probable violation by any J&J Pharmaceutical Affiliate of criminal, civil, or administrative laws applicable to any federal health

[44] *Id.* at 11, Section III.B.1 (defining "Code of Conduct").
[45] *Id.*
[46] *Id.* at 2, Section II.C.2.a.
[47] *See id.* at 10, Section III.B.1.c.

care program, and/or any FDA requirements relating to the promotion of Government Reimbursed Products, for which penalties or exclusion may be authorized."[48]

156. The CIA also established a duty and obligation to pay the Government money, in the form of stipulated penalties, which arise from J&J's contractually-binding requirement to report instances of fraudulent conduct.

157. Specifically, the CIA contains a section entitled "Breach and Default Provisions," which provides "Stipulated Penalties" as a contractual remedy for any failure by J&J to comply with the obligations under the CIA.[49] These stipulated penalties include, *inter alia*:

- "A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day J&J fails to establish and implement any of the following obligations," including, but not limited to, "a Disclosure Program" as required by Section III.F.[50]
- "A Stipulated Penalty of $5,000 for each false certification submitted by or on behalf of J&J as part of its Implementation Report, or any Annual Report, additional documentation to a report, or otherwise required by this CIA"[51]; and
- "A Stipulated Penalty of $1,000 for each day J&J fails to comply fully and adequately with any obligation of this CIA."[52]

B. J&J KNOWINGLY FAILED TO COMPLETELY AND TRUTHFULLY REPORT ALL "REPORTABLE EVENTS" IN COMPLIANCE WITH ITS CIA

158. J&J has knowingly failed to completely and truthfully certify its compliance with its CIA, and failed to completely and truthfully report all "reportable events" in compliance with

[48] *See id.* at 33, Section III.J.1. J&J.
[49] *See id.* at 59-66, Section X; *id.* at 59-62, Section X.A.
[50] *See* J&J CIA at 60, Section X.A.1.i.
[51] *See id.* at 61, Section X.A.6.
[52] *See id.* at 61, Section X.A.7.

the CIA. Thus, J&J has knowingly, deliberately and without just cause presented or caused to be presented false certifications or claims under 31 U.S.C. §§ 3729 *et seq*.

159. As a result of J&J's unlawful conduct, the United States has been damaged, and continues to be damaged, by Government Program payments for illegally promoted Remicade and Simponi Aria prescriptions.

VIII. J&J CARRIED OUT ITS KICKBACK SCHEME IN KNOWING DISREGARD OF ITS DUTY TO COMPLY WITH THE AKS AND IN FLAGRANT VIOLATION OF ITS OWN COMPLIANCE RULES

160. J&J was well aware that the AKS applied to its use of rebates and other monies to promote the sale of Remicade and Simponi Aria to the Health Care Providers and that it had an obligation to ensure that its rebate and discount relationships complied with the AKS. Nonetheless, in pursuit of the profits associated with higher sales, J&J chose to disregard its duty to comply with the AKS. Indeed, to reap the growth in Remicade and Simponi Aria sales produced by the kickbacks, J&J not only ignored its compliance obligations, but also violated its own compliance policies and requirements.

161. For example, J&J states as a matter of written policy the following concerning its "Ethical Sales & Marketing Practices":

> At Johnson & Johnson, we are committed to responsible, ethical and patient-centered sales and marketing practices for our Consumer, Pharmaceutical and Medical Devices products and services. Our sales and marketing efforts seek to inform health decisions and consumer choices.
>
> Our Credo guides all Johnson & Johnson employees to put the needs and well-being of the people we serve first, ethically and with integrity. We strive to operate with the highest standards of business conduct and transparency through all communications with patients, consumers, healthcare professionals (HCPs) and other stakeholders.

162. J&J was well aware of its legal obligations regarding compliance with the AKS and the FCA, declaring the following with regard to "Responsible Interaction with Health Care Professions":

> To help ensure the integrity of the relationship between our representatives and doctors, our guidelines are based on industry codes of conduct as well as the legal, regulatory and professional requirements of the countries where we do business. Among these are:
>
> U.S. federal Anti-Kickback statute that prohibits improper influence in healthcare decision-making by making it a crime to knowingly and willfully offer, give or receive anything of value in order to influence or obtain government healthcare business.
>
> U.S. federal False Claims Act that prohibits making or inducing someone else to make a false claim for reimbursement from the federal government.

163. Its 2017 version of its "Code of Business Conduct," which was issued by J&J and distributed to employees of its U.S. subsidiaries, made clear its position that the Company "would not engage in the payment of bribes, kickbacks, illegal payments or any other offer of items of value that may inappropriately influence or reward a customer to order, purchase or use our products and services, whether provided directly or through a third party such as a distributor, customs broker or other agent."

164. Likewise, its Code of Conduct stated unequivocally that "[w]e also interact with government regulators and inspection authorities. It is our duty to follow local and internationally applicable laws and ethical standards prohibiting bribery and corruption and to avoid inappropriately influencing the medical decisions of the Health Care Providers and the purchasing decisions of entities that buy our products and services."

165. J&J ignored not only the spirit of its Code of Business Conduct, but also its letter by engaging the conduct alleged herein. While the J&J executives' clear disregard of Company policies in their negotiations with physicians, the GPO Defendants, home infusion companies

and stand-alone infusion centers was based on their specific goal of protecting Remicade from biosimilars, this conduct was emblematic of a general philosophy at J&J of putting sales and profits before compliance. Indeed, as set forth above, J&J knowingly implemented a strategy that was premised, in key part, on using kickbacks, under the guise of "performance" rebates and other monies, to induce the Health Care Providers to purchase or to recommend Remicade, Simponi Aria in plain violation of the AKS.

166. As alleged in this Complaint, J&J has knowingly and repeatedly violated the federal AKS and state analogues in the promotion of its drugs products Remicade and Simponi Aria. These violations have not been incidental, but instead have been central to the Company's sales strategy.

IX. THE DEFENDANTS VIOLATED THE CIFPA

167. J&J's schemes targeted and defrauded California private health insurance companies and other health benefits providers, including, without limitation, health benefit plans, health maintenance organizations, purchasing alliances, carriers, employers, pharmacy benefit managers, third party administrators and managed care organizations (collectively, "MCOs") on a massive scale. J&J's fraudulent practices caused doctors to write prescriptions for J&J drugs that they otherwise would not have written and caused MCOs to pay reimbursement claims for prescriptions of J&J drugs that they otherwise would not have paid.

168. MCOs are an organized means of providing patients access to quality health care, while maintaining a special focus on keeping health benefits costs, such as a prescription drug benefit, under control. By keeping costs down, MCOs are able to control premiums and patient cost-sharing. To achieve these goals, MCOs utilize a number of cost-containment policies, including favoring utilization of cheaper biosimilar drugs instead of wildly expensive drugs like

Remicade and Simponi Aria. While MCOs will sometimes reimburse expensive branded drugs instead of cheaper biosimilars, they typically require a showing that the drugs are medically necessary for the particular patient in question through a procedure called "prior authorization."

169. Rather than work with MCOs to gain coverage for its drugs, J&J chose instead to deceive them. J&J's primary tactic has been to deploy its sales force to essentially bribe doctors to prescribe J&J drugs Remicade and Simponi Aria.

170. J&J's fraudulent scheme was executed nationwide, but California—which is the largest pharmaceutical market in the nation—was its epicenter.

171. This action is brought on behalf of the People of the State of California to recover reimbursements made by MCOs responsible for reimbursing the J&J drugs. As a result of the fraudulent and deceptive conduct described in this Complaint, the MCOs have incurred millions of dollars in extra costs, thereby injuring the millions of beneficiaries, employers and other health benefit sponsors which seek to control prescription drug costs. These MCOs insure and/or administer health benefits for an estimated 60% or more of California's insured population.

A. THE CALIFORNIA INSURANCE FRAUDS PREVENTION ACT

172. The California legislature enacted the CIFPA to combat abusive practices aimed at defrauding private insurance providers. The legislature made clear that it was specifically concerned with fraud on health insurance providers, stating: "Health insurance fraud is a particular problem for health insurance policyholders. Although there are no precise figures, it is believed that fraudulent activities account for billions of dollars annually in added health care costs nationally. Health care fraud causes losses in premium dollars and increases health care costs unnecessarily." Cal. Ins. Code § 1871(h).

173. The CIFPA subjects any person who violates Cal. Ins. Code § 1871.7(a), or Sections 549, 550, or 551 of the California Penal Code (each addressed sequentially below), to civil penalties of between $5,000 and $10,000, plus an assessment of not more than three times the amount of each claim for compensations, as defined pursuant to a contract of insurance. Cal. Ins. Code § 1871.7(b). The CIFPA also vests the court with "the power to grant other equitable relief, including temporary injunctive relief, as is necessary to prevent the transfer, concealment, or dissipation of illegal proceeds, or to protect the public." *Id.*

174. Cal. Ins. Code § 1871.7(a) prohibits the knowing employment of "runners, cappers, steerers or other persons to procure clients or patients … to perform or obtain services or benefits under a contract of insurance or that will be the basis for a claim against an insured individual or his or her insurer."

175. California Penal Code § 549 makes it illegal for any firm or corporation to "solicit[], accept[], or refer[] any business to or from any individual or entity with the knowledge that, or with reckless disregard for whether" that individual intends to make or cause to be made any false or fraudulent claim for payment of a health care benefit.

176. California Penal Code § 550(a)(5) makes it unlawful to "[k]nowingly prepare, make, or subscribe any writing, with the intent to present or use it, or to allow it to be presented, in support of any false or fraudulent claim," or to aid, abet, solicit, or conspire with any person to do the same.

177. California Penal Code § 550(a)(6) makes it unlawful to "[k]nowingly make or cause to be made any false or fraudulent claim for payment of a health care benefit," or to aid, abet, solicit, or conspire with any person to do the same.

178. California Penal Code § 550(b)(1) makes it unlawful to "[p]resent or cause to be presented any written or oral statement as part of, or in support of or opposition to, a claim for payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false or misleading information concerning any material fact," or to knowingly assist or conspire with any person to do the same.

179. California Penal Code § 550(b)(2) makes it unlawful to "[p]repare or make any written or oral statement that is intended to be presented to any insurer or any insurance claimant in connection with, or in support of or opposition to, any claim or payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false or misleading information concerning any material fact," or to knowingly assist or conspire with any person to do the same.

180. In addition, California Business & Professional Code § 650(a) provides that "the offer, delivery, receipt, or acceptance by any person licensed under this division … of any rebate, refund, commission, preference, patronage dividend, discount, or other consideration, whether in the form of money or otherwise, as compensation or inducement for referring patients, clients, or customers to any person, irrespective of any membership, proprietary interest, or co-ownership in or with any person to whom these patients, clients, or customers are referred, is unlawful."

181. Unlike the federal AKS, there is no requirement in section 650 requiring that a violation be committed "knowingly" or "willfully." "The violation of section 650 is a general intent crime, requiring proof only that the defendant offered consideration as inducement for referrals; no specific intent is required." *People v. Guiamelon*, 205 Cal. App. 4th 383, 399-400, 140 Cal. Rptr. 3d 584, 595 (Cal. Ct. App. 2012) (citing *People v. Hering*, 20 Cal. 4th 440, 447, 84 Cal. Rptr. 2d 839, 976 P.2d 210 (1999) (Section 650 was enacted (1) to ensure that referrals

would not be induced by considerations other than the best interest of the patient and (2) to prevent patients being charged more for treatment because of an additional hidden fee imposed to recoup payment for securing the referral. *Id.* at 400, 140 Cal. Rptr. 3d at 595 (citations and internal quotation marks omitted).

182. Through the fraudulent scheme, alleged *infra*, J&J and the Health Care Providers violated the preceding provisions, making or causing fraudulent health care claims to be made to California MCOs. By doing so, J&J and the Health Care Providers substantially and illegally increased California MCOs' costs and in turn increased the costs of their participants' coverage.

B. MANAGED CARE ORGANIZATIONS AND COST-CONTAINMENT STRATEGIES

183. The goal of California MCO health care coverage is to provide appropriate, affordable and accessible services and products in order to achieve positive short-term and long-term patient outcomes.

184. California MCOs routinely use a variety of tools and strategies, frequently in tandem, to achieve the goals of making available services and goods appropriate for the varied needs of beneficiaries, while managing costs for both beneficiaries and plan sponsors.

185. As alleged in this Complaint, J&J's fraudulent scheme was intended to and did interfere with California MCOs' cost control programs by inducing health care professionals to prescribe, recommend, and/or fill prescriptions for Remicade and Simponi Aria manufactured by J&J.

C. J&J USE OF KICKBACKS TO DEFRAUD CALIFORNIA MANAGED CARE ORGANIZATIONS

186. Pharmaceuticals play an important role in the prevention, cure, and management of disease. At the same time, expenditures for drugs have been and are expected to continue to

increase at rates higher than or comparable to expenditures for other health-related products and services.

187. A primary focus of California MCOs is to lower their expenditures on pharmaceuticals. In doing so, they save money for both plan sponsors and patients who pay the premiums, and ultimately help ensure the affordability and sustainability of drug benefit coverage.

188. As alleged in this Complaint, J&J's fraudulent schemes were intended to and did interfere with California MCOs' cost control programs by inducing health care professionals to prescribe, and/or to fill prescriptions with, higher cost J&J brand name drugs instead of cheaper, equivalent biosimilar drugs.

189. As alleged in this Complaint, J&J's kickback schemes were intended to, and did, circumvent the cost-control measures California MCOs sought to achieve through their provider agreements. J&J caused doctors to write prescriptions that did not comply with the certifications the doctors made in their provider agreements. And J&J provided financial inducements to doctors to prescribe J&J products that offset the financial incentives MCOs provided for doctors to prescribe more cost-effective generic drugs.

D. COMPETITIVE CHOICE AS A COST-CONTAINMENT STRATEGY

190. A fundamental aspect of California MCOs' cost-containment strategies is to ensure the availability of competitive services and products, grounded in the economic principle that free-market competition will keep prices down.

191. J&J's practices deprived California MCOs and their beneficiaries of the pricing and selection benefits of free-market competition.

192. J&J's practices also deprived California MCOs and their beneficiaries of the independent judgment of various healthcare professionals in the relevant health care sector (including rheumatologists, dermatologists, infusion centers, and GPOs). Instead, the California MCOs' beneficiaries were steered or compelled to use J&J products without regard to whether the J&J products were the best and/or most economical products for the beneficiaries' needs.

E. CALIFORNIA MCOS PROVIDER AGREEMENTS AND MANUALS

193. California MCOs also attempt to control costs through the terms of their "provider" agreements, as set forth in the Provider Application/Agreement and in the Provider Manual. Collectively, those documents are the contracts MCOs require Health Care Providers to sign and be bound by before the California MCO will cover the services or goods.

194. For example, provider agreements universally require the provider to certify that he or she will provide covered patients with medical services that are "Medically Necessary." As one authority noted, "a common definition among insurers" is that goods and services are "Medically Necessary" only if it is "not more costly than an alternative service or sequence of services that is at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patients' illness, injury, or disease."

195. The current Blue Shield Provider Manual, similarly includes in its definition of "Medically Necessary" that "[i]f there are two or more Medically Necessary services that may be provided for the illness, injury or medical condition, Blue Shield will provide benefits based on the most cost-effective services."[53]

196. Provider agreements also require providers to certify that they will provide services in accordance with the law. For example, Blue Shield of California's Independent

[53] Blue Shield of California Independent Physician and Provider Manual, at Appendix 1-A Page 14.

Physician and Provider Agreement contains a section entitled "Representations and Warranties of Provider." Among those representations and warranties, the provider must certify that it will "comply with applicable state and federal laws and regulations," and will "be in compliance with all applicable local, state and federal laws relating to the provision of services hereunder, and furnish such services in accordance with all applicable licensing requirements and all local standards of professional ethics and practice."

197. Similarly, the Blue Shield of California Provider Manual notes that all physicians entering into an agreement to provide services to the insurer's subscribers or enrollees are deemed a "Physician Member" of Blue Shield of California and "shall be bound by the Bylaws, schedules of compensation for services rendered, and rules and regulations of the corporation." Blue Shield of California Independent Physician and Provider Manual, at Appendix 2 Page 2 of Bylaws. In turn, the rules and regulations of the corporation include the following prohibition against kickbacks, fraud, waste and abuse:

> Blue Shield's Code of Conduct and the Corporate Compliance Program Blue Shield is subject to a wide variety of federal, state, and local laws. These include, but are not limited to, laws governing confidentiality of medical records, personally identifiable information, health plan and insurance regulatory requirements, government contracts, kickbacks, fraud, waste, and abuse, false claims and provider payments.

Blue Shield of California Independent Physician and Provider Manual, at Section 1 Page 18.[54]

198. The insurers also have the right to enforce these requirements through audits of the provider's billing and other practices affecting the integrity of the claims submitted to the insurer for payment. For example, Blue Shield of California expressly notes its right to conduct

[54] The provider manuals of other insurers contain similar provisions. E.g., OptumHealth Care Solutions, Inc., Provider Operations Manual, at 20 (rev. Jan. 2016) (prohibiting "[s]oliciting, offering or receiving a kickback or bribe." Applicable to CAN Group of California, Inc., d/b/a/ OptumHealth Physical Health of California, available at https://www.myoptumhealthphysicalhealth.com/documents/OperationsManual.pdf); MARCH Vision Care, Provider Reference Guide, at 32-33 (prohibiting kickbacks).

provider audits to ensure the provider's compliance with "state and federal laws and regulations."[55]

199. A number of California MCOs also have programs under their provider agreements in which doctors are offered financial incentives for meeting certain performance goals in furtherance of cost-containment objectives.

200. As alleged in this Complaint, J&J's kickback scheme was intended to, and did, circumvent the cost-control measures California MCOs sought to achieve through their provider agreements. In particular, J&J's payments of kickbacks to the Health Care Providers: caused those Health Care Providers to write and/or fill prescriptions for the J&J drugs that did not comply with the certifications made in the provider agreements, and undermined the financial incentives offered by the California MCOs to the Health Care Providers designed to further cost containment objectives.

F. J&J Caused False Claims To Be Submitted To California MCOs

201. J&J provided Health Care Providers with performance rebates for the purpose of illegally inducing and/or rewarding those providers to purchase Remicade and/or Simponi Aria for use treating beneficiaries of various California MCOs. These kickbacks were intended to (and did) induce purchasing, ordering, arranging for or recommending purchasing or ordering of goods or items for which payment was made by California MCOs, in violation of the California Insurance Frauds Prevention Act, Cal. Ins. Code § 1871.7(b).

202. These kickbacks caused Health Care Providers to use J&J's products rather than cheaper competitor biosimilars.

[55] Blue Shield of California Independent Physician and Provider Manual, at Section 1 Page 15.

203. Claims that were submitted to California MCOs as a result, in part or in whole, based on kickbacks provided by J&J, were therefore false within the meaning of the CIFPA.

204. J&J's payment of kickbacks therefore caused the submission of claims that were false and not eligible for reimbursement to California MCOs.

205. J&J's payment and offers of payment of kickbacks were made knowingly and with the intent to cause the submission of false claims to California MCOs.

206. California MCOs paid reimbursements for those false claims, and as a result have incurred and continue to incur significant damages due to J&J's illegal payment of kickbacks.

COUNT I
(Violation of False Claims Act, 31 U.S.C. § 3729(a)(1); 31 U.S.C. § 3729(a)(1)(A))

207. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

208. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to the United States of America false or fraudulent claims for payment or approval, in violation of 31 U.S.C. § 3729(a)(1) and 31 U.S.C. § 3729(a)(1)(A).

209. As a result of Defendants' actions, as set forth above, the United States of America has been, and may continue to be, severely damaged.

COUNT II
(Violation of False Claims Act, 31 U.S.C. § 3729(a)(2); 31 U.S.C. § 3729(a)(1)(B))

210. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

211. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements material to the payment of false or fraudulent claims, in violation of 31 U.S.C. § 3729(a)(2); 31 U.S.C. § 3729(a)(1)(B).

212. J&J's false and fraudulent statements, including with respect to the safety and efficacy, superiority, and medical necessity and appropriateness of its drugs, to the public, to patients, to the Health Care Providers, and directly to Medicaid and other federal health care programs, were material to the Health Care Providers' decisions to prescribe these drugs and the United States' decisions to pay claims for these drugs and related services.

213. The United States, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid and may continue to be paying or reimbursing for Remicade and Simponi Aria prescribed to patients enrolled in federal Programs.

214. As a result of Defendants' actions, as set forth above, the United States of America has been, and may continue to be, severely damaged.

COUNT III
(Violation of False Claims Act, 31 U.S.C. § 3729(a)(3); 31 U.S.C. § 3729(a)(1)(C))

215. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

216. As alleged above, Defendants knowingly conspired, and may still be conspiring, with the Health Care Providers and others, including those identified and alleged herein, to commit acts in violation of 31 U.S.C. §§ 3729(a)(1) & (a)(2); 31 U.S.C. §§ 3729(a)(1)(A) &

(a)(1)(B). Defendants and the Health Care Providers committed overt acts in furtherance of the conspiracy as alleged above.

217. As a result of Defendants' actions, as set forth above, the United States of America has been, and may continue to be, severely damaged.

COUNT IV
(Violation of False Claims Act, 31 U.S.C. § 3729(a)(1)(G))

218. Relator realleges and incorporates by reference all prior paragraphs.

219. As alleged above, Defendants knowingly made, used, and/or caused to be made or used, false records or statements material to an obligation to pay or transmit money or property to the Government, and/or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government pursuant to § 3729(a)(1)(G).

220. As a result of Defendants' action as set forth above, the United States of America has been, and may continue to be, severely damaged.

COUNT V
(Violation of California False Claims Act)

221. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

222. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of Cal. Gov't Code § 12651(a)(1).

223. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Cal. Gov't Code § 12651(a)(2).

224. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of California, or its political subdivisions, in violation of Cal. Gov't Code § 12651(a)(7).

225. The State of California, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state and state subdivision funded health insurance programs.

226. As a result of Defendants' actions, as set forth above, the State of California and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT VI
(Violation of Colorado Medicaid False Claims Act)

227. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

228. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an

officer or employee of the State of Colorado, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Colo. Rev. Stat. § 25.5-4-305(a).

229. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Colo. Rev. Stat. § 25.5-4-305(b).

230. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Colorado, or its political subdivisions, in violation of Colo. Rev. Stat. § 25.5-4-305(f).

231. The State of Colorado, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state and state subdivision funded health insurance programs.

232. As a result of Defendants' actions, as set forth above, the State of Colorado and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT VII
(Violation of Connecticut False Claims Act for Medical Assistance Programs)

233. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

234. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Connecticut, or its political subdivisions, false or fraudulent claims for payment or approval under a medical assistance program administered by the Department of Social Services, in violation of Conn. Gen. Stat. § 17b-301b(1).

235. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to secure the payment or approval by the State of Connecticut, or its political subdivisions, false or fraudulent claims under a medical assistance program administered by the Department of Social Services, in violation of Conn. Gen. Stat. § 17b-301b(2).

236. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Connecticut, or its political subdivisions, under a medical assistance program administered by the Department of Social Services, in violation of Conn. Gen. Stat. § 17b-301b(7).

237. The State of Connecticut, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-

related management services for recipients of state and state subdivision funded health insurance programs.

238. As a result of Defendants' actions, as set forth above, the State of Connecticut and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT VIII
(Violation of Delaware False Claims and Reporting Act)

239. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

240. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Delaware, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Del. Code Ann. tit. 6, § 1201(a)(1).

241. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Delaware, or its political subdivisions, in violation of Del. Code Ann. tit. 6, § 1201(a)(2).

242. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Delaware, or its political subdivisions, in violation of Del. Code Ann. tit. 6, § 1201(a)(7).

243. The State of Delaware, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health care programs funded by the State of Delaware.

244. As a result of Defendants' actions, as set forth above, the State of Delaware and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT IX
(Violation of District of Columbia False Claims Act)

245. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

246. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the District, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of D.C. Code § 2-308.14(a)(l).

247. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be used, and may still be making, using, or causing to be made or used, false records or statements to get false claims paid or approved by the District, or its political subdivisions, in violation of D.C. Code § 2-308.14(a)(2).

248. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made

or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the District, or its political subdivisions, in violation of D.C. Code § 2-308.14(a)(7).

249. The District of Columbia, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the District.

250. As a result of Defendants' actions, as set forth above, the District of Columbia and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT X
(Violation of Florida False Claims Act)

251. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

252. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Florida, or its agencies, false or fraudulent claims for payment or approval, in violation of Fla. Stat. § 68.082(2)(a).

253. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Florida, or its agencies, in violation of Fla. Stat. § 68.082(2)(b).

254. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Florida, or its agencies, in violation of Fla. Stat. § 68.082(2)(g).

255. The State of Florida, or its agencies, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance plans funded by the State of Florida or its agencies.

256. As a result of Defendants' actions, as set forth above, the State of Florida and/or its agencies have been, and may continue to be, severely damaged.

COUNT XI
(Violation of Georgia False Medicaid Claims Act)

257. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

258. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to the Georgia Medicaid program false or fraudulent claims for payment or approval, in violation of Ga. Code Ann. § 49-4-168.1(a)(1).

259. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made

or used, false records or statements to get false or fraudulent claims paid or approved by the Georgia Medicaid program, in violation of Ga. Code Ann. § 49-4-168.1(a)(2).

260. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Georgia, or its political subdivisions, in violation of Ga. Code Ann. § 49-4-168.1(a)(7).

261. The State of Georgia, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

262. As a result of Defendants' actions, as set forth above, the State of Georgia and/or political subdivisions have been, and may continue to be, severely damaged.

COUNT XII
(Violation of Hawaii False Claims Act)

263. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

264. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Hawaii, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Haw. Rev. Stat. § 661-21(a)(l).

265. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made and used, and may still be making, using, or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Hawaii, or its political subdivisions, in violation of Haw. Rev. Stat. § 661-21(a)(2).

266. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Hawaii, or its political subdivisions, in violation of Haw. Rev. Stat. § 661-21(a)(7).

267. The State of Hawaii, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state-funded health insurance programs.

268. As a result of Defendants' actions, as set forth above, the State of Hawaii and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XIII
(Violation of Illinois False Claims Act)

269. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

270. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(A).

271. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements material to get false or fraudulent claims paid or approved by the State of Illinois, or its political subdivisions, in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(B).

272. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements material to conceal, avoid or decrease an obligation to pay or transmit money to the State of Illinois, or its political subdivisions, in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(G).

273. The State of Illinois, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of those claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state-funded health insurance programs.

274. As a result of Defendants' actions, as set forth above, the State of Illinois and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XIV
(Violation of Indiana False Claims and Whistleblower Protection Act)

275. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

276. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally presented, or caused to be presented, and may still be presenting or causing to be presented, false claims to the State of Indiana, or its political subdivisions, for payment or approval, in violation of Ind. Code § 5-11-5.5-2(b)(l).

277. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to obtain payment or approval of false claims from the State of Indiana, or its political subdivisions, in violation of Ind. Code § 5-11-5.5-2(b)(2).

278. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to avoid an obligation to pay or transmit money to the State of Indiana, or its political subdivisions, in violation of Ind. Code § 5-11-5.5-2(b)(6).

279. The State of Indiana, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of those claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state-funded health insurance programs.

280. As a result of Defendants' actions, as set forth above, the State of Indiana and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XV
(Violation of Iowa False Claims Act)

281. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

282. Defendants, in reckless disregard or deliberate ignorance for the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of Iowa Code § 685.2(1)(a).

283. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Iowa Code § 685.2(1)(b).

284. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still me making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Iowa, or its political subdivisions, in violation of Iowa Code § 685.2(1)(g).

285. The State of Iowa, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the State or its political subdivisions.

286. As a result of Defendants' actions, as set forth above, the State of Iowa and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XVI
(Violation of Louisiana Medical Assistance Programs Integrity Law)

287. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

288. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims, in violation of La. Rev. Stat. Ann. § 46:438.3(A).

289. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly engaged in misrepresentation, and may still be engaging in misrepresentation, to obtain, or attempt to obtain, payment from medical assistance programs funds, in violation of La. Rev. Stat. Ann. § 46:438.3(B).

290. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly submitted, and may continue to submit, claims for goods, services or supplies which were medically unnecessary or which were of substandard quality or quantity, in violation of La. Rev. Stat. Ann. § 46:438.3(D).

291. The State of Louisiana, its medical assistance programs, political subdivisions and/or the Department, unaware of the falsity of the claims and/or statements made by Defendants, or their actions as set forth above, acted in reliance, and may continue to act in reliance, on the accuracy of Defendants' claims and/or statements in paying for prescription drugs and prescription drug-related management services for medical assistance program recipients.

292. As a result of Defendants' actions, as set forth above, the State of Louisiana, its medical assistance programs, political subdivisions and/or the Department have been, and may continue to be, severely damaged.

COUNT XVII
(Violation of Maryland False Health Claims Act)

293. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

294. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of MD, tit. 2 § 2-602(a)(1).

295. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to obtain payment or approval of claims by the State of Maryland, or its political subdivisions, in violation of MD, tit. 2 § 2-602(a)(2).

296. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Maryland, or its political subdivisions, in violation of MD, tit. 2 § 2-602(a)(7).

297. The State of Maryland, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims

and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the State or its political subdivisions.

298. As a result of Defendants' actions, as set forth above, the State of Maryland and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XVIII
(Violation of Massachusetts False Claims Act)

299. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

300. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of Mass. Gen. Laws ch. 12 § 5B(1).

301. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to obtain payment or approval of claims by the Commonwealth of Massachusetts, or its political subdivisions, in violation of Mass. Gen. Laws ch. 12 § 5B(2).

302. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit

money to the Commonwealth of Massachusetts, or its political subdivisions, in violation of Mass. Gen. Laws ch. 12 § 5B(8).

303. The Commonwealth of Massachusetts, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the State or its political subdivisions.

304. As a result of Defendants' actions, as set forth above, the Commonwealth of Massachusetts and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XIX
(Violation of Michigan Medicaid False Claims Act)

305. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

306. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and may still be making or causing to be made, false statements or false representations of material facts in an application for Medicaid benefits, in violation of Mich. Comp. Laws § 400.603(1).

307. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made false statements or false representations of a material fact for use in determining rights to a Medicaid benefit, in violation of Mich. Comp. Laws § 400.603(2).

308. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly concealed or failed to disclose, and may still be concealing or failing to disclose, an event affecting its initial or continued right to receive a Medicaid benefit, or the initial or continued right of any other person on whose behalf Defendants has applied for or is receiving a benefit with intent to obtain a benefit to which Defendants were not entitled or in an amount greater than that to which Defendants were entitled, in violation of Mich. Comp. Laws § 400.603(3).

309. Defendants, in possession of facts under which they are aware or should be aware of the nature of their conduct and that their conduct is substantially certain to cause the payment of a Medicaid benefit, knowingly made, presented or caused to be made or presented, and may still be presenting or causing to be presented, to an employee or officer of the State of Michigan, or its political subdivisions, false claims under the Social Welfare Act, Mich. Comp. Laws §§ 400.1-400.122, in violation of Mich. Comp. Laws § 400.607(1).

310. The State of Michigan, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

311. As a result of Defendants' actions, as set forth above, the State of Michigan and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XX
(Violation of Minnesota False Claims Act)

312. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

313. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Minnesota, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Minn. Stat. § 15C.02(a)(1).

314. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to get false or fraudulent claim paid or approved by the State of Minnesota, or its political subdivisions, in violation of Minn. Stat. § 15C.02(a)(2).

315. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Minnesota, or its political subdivisions, in violation of Minn. Stat. § 15C.02(a)(7).

316. The State of Minnesota, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of State and State subdivision funded health insurance programs.

317. As a result of Defendants' actions, as set forth above, the State of Minnesota and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXI
(Violation of Montana False Claims Act)

318. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

319. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Montana, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Mont. Code Ann. § 17-8-403(1)(a).

320. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Montana, or its political subdivisions, in violation of Mont. Code Ann. § 17-8-403(1)(b).

321. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Montana, or its political subdivisions, in violation of Mont. Code Ann. § 17-8-403(1)(g).

322. The State of Montana, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-

related management services for recipients of health insurance programs funded by the State or its political subdivisions.

323. As a result of Defendants' actions, as set forth above, the State of Montana and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXII
(Violation of Nevada False Claims Act)

324. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

325. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false claims for payment or approval, in violation of Nev. Rev. Stat. § 357.040(1)(a).

326. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to obtain payment or approval of false claims, in violation of Nev. Rev. Stat. § 357.040(1)(b).

327. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Nevada, or its political subdivisions, in violation of Nev. Rev. Stat. § 357.040(1)(g).

328. The State of Nevada, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the State or its political subdivisions.

329. As a result of Defendants' actions, as set forth above, the State of Nevada and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXIII
(Violation of New Hampshire False Claims Act)

330. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

331. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of NH Stat. Ann § 167:61-b(I)(a).

332. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to obtain payment or approval of claims by the State of New Hampshire, or its political subdivisions, in violation of NH Stat. Ann § 167:61-b(I)(b).

333. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit

money to the State of New Hampshire, or its political subdivisions, in violation of NH Stat. Ann § 167:61-b(I)(e).

334. The State of New Hampshire, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the State or its political subdivisions.

335. As a result of Defendants' actions, as set forth above, the State of New Hampshire and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXIV
(Violation of New Jersey False Claims Act)

336. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

337. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally presented or caused to be presented, and may still be presenting or causing to be presented, to an employee, officer or agent of the State of New Jersey, or to any contractor, grantee, or other recipient of State funds, false or fraudulent claims for payment or approval, in violation of N.J. Stat. Ann. § 2A:32C-3(a).

338. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to made or used, and may still be making, using, or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of New Jersey, or its political subdivisions, in violation of N.J. Stat. Ann. § 2A:32C-3(b).

339. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New Jersey, or its political subdivisions, in violation of N.J. Stat. Ann. § 2A:32C-3(g).

340. The State of New Jersey, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

341. As a result of Defendants' actions, as set forth above, the State of New Jersey and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXV
(Violation of New Mexico Medicaid False Claims Act)

342. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

343. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to the State of New Mexico, or its political subdivisions, false or fraudulent claims for payment under the Medicaid program, in violation of N.M. Stat. Ann. § 27-14-4(A).

344. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made

or used, false records or statements to obtain false or fraudulent claims under the Medicaid program paid for or approved by the State of New Mexico, or its political subdivisions, in violation of N.M. Stat. Ann. § 27-14-4(C).

345. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New Mexico, or its political subdivisions, relative to the Medicaid program, in violation of N.M. Stat. Ann. § 27-14-4(E).

346. The State of New Mexico, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the State or its political subdivisions.

347. As a result of Defendants' actions, as set forth above, the State of New Mexico and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXVI
(Violation of New York False Claims Act)

348. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

349. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of N.Y. State Fin. Law § 189(1)(a).

350. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of N.Y. State Fin. Law § 189(1)(b).

351. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements material to an obligation to pay or transmit money to the State of New York, or its political subdivisions, in violation of N.Y. State Fin. Law § 189(1)(g).

352. The State of New York, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the State or its political subdivisions.

353. As a result of Defendants' actions, set forth above, the State of New York and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXVII
(Violation of North Carolina False Claims Act)

354. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

355. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of N.C. Gen. Stat. § 1-607(a)(1).

356. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of N.C. Gen. Stat. § 1-607(a)(2).

357. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of North Carolina, or its political subdivisions, in violation of N.C. Gen. Stat. § 1-607(a)(7).

358. The State of North Carolina, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the State or its political subdivisions.

359. As a result of Defendants' actions, as set forth above, the State of North Carolina and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXVIII
(Violation of Oklahoma Medicaid False Claims Act)

360. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

361. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Oklahoma, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Okla. Stat. tit. 63, § 5053.1(B)(1).

362. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and may still be making or causing to be made, false records or statements to get false or fraudulent claims paid or approved by the State of Oklahoma, or its political subdivisions, in violation of Okla. Stat. tit. 63, § 5053.1(B)(2).

363. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Oklahoma, or its political subdivisions, in violation of Okla. Stat. tit. 63, § 5053.1(B)(7).

364. The State of Oklahoma, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

365. As a result of Defendants' actions, as set forth above, the State of Oklahoma and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXIX
(Violation of Rhode Island False Claims Act)

366. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

367. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Rhode Island or a member of Rhode Island's National Guard, false or fraudulent claims for payment or approval, in violation of R.I. Gen. Laws § 9-1.1-3(a)(1).

368. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and may still be making or causing to be made, false records or statements to get false or fraudulent claims paid or approved by the State of Rhode Island, or its political subdivisions, in violation of R.I. Gen. Laws § 9-1.1-3(a)(2).

369. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Rhode Island, or its political subdivisions, in violation of R.I. Gen. Laws § 9-1.1-3(a)(7).

370. The State of Rhode Island, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims

and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

371. As a result of Defendants' actions, as set forth above, the State of Rhode Island and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXX
(Violation of Tennessee Medicaid False Claims Act)

372. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

373. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to the State of Tennessee, or its political subdivisions, false or fraudulent claims for payment under the Medicaid program, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(A).

374. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false or fraudulent records or statements to get false or fraudulent claims under the Medicaid program paid for or approved by the State of Tennessee, or its political subdivisions, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(B).

375. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false or fraudulent records or statements to conceal, avoid or decrease an obligation to

pay or transmit money to the State of Tennessee, or its political subdivisions, relative to the Medicaid program, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(D).

376. The State of Tennessee, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of the Medicaid program.

377. As a result of Defendants' actions, as set forth above, the State of Tennessee and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXXI
(Violation of Texas Medicaid Fraud Prevention Act)

378. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

379. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and may still be making or causing to be made, false statements or misrepresentations of material fact that permitted Defendants to receive a benefit or payment under the Medicaid program that was not authorized or that was greater than the benefit or payment that was authorized, in violation of Tex. Hum. Res. Code Ann. § 36.002(1).

380. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly concealed or failed to disclose, or caused to be concealed or not disclosed — and may still be concealing or failing to disclose, or causing to be concealed or not disclosed — information that permitted Defendants to receive a benefit or payment under the Medicaid program that was not

authorized or that was greater than the payment that was authorized, in violation of Tex. Hum. Res. Code Ann. § 36.002(2).

381. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, caused to be made, induced or sought to induce, and may still be making, causing to be made, inducing or seeking to induce, false statements or misrepresentations of material fact concerning information required to be provided by a federal or State law, rule, regulation or physician agreement pertaining to the Medicaid program, in violation of Tex. Hum. Res. Code Ann. § 36.002(4)(B).

382. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, and may still be making, claims under the Medicaid program for services or products that were inappropriate, in violation of Tex. Hum. Res. Code Ann. § 36.002(7)(C).

383. The State of Texas, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

384. As a result of Defendants' actions, as set forth above, the State of Texas and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXXII
(Violation of Texas Medical Assistance Program, Damages, and Penalties Act)

385. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

386. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of Tex. Hum. Res. Code. Ann. § 32.039(b)(1).

387. Defendants solicited or received and may still be soliciting or receiving, directly or indirectly, overtly or covertly any remuneration, including any kickback, bribe, or rebate, in cash or in kind for purchasing, leasing, or ordering, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item for which payment may be made, in whole or in part, under the medical assistance program by the State of Texas, or its political subdivisions, in violation of Tex. Hum. Res. Code. Ann. § 32.039(b)(1-c).

388. Defendants offered or paid and may still be offering or paying, directly or indirectly, overtly or covertly any remuneration, including any kickback, bribe, or rebate, in cash or in kind to induce a person to purchase, lease, or order, or arrange for or recommend the purchase, lease, or order of, any good, facility, service, or item for which payment may be made, in whole or in part, under the medical assistance program by the State of Texas, or its political subdivisions, in violation of Tex. Hum. Res. Code. Ann. § 32.039(b)(1-e).

389. The State of Texas, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the State or its political subdivisions.

390. As a result of Defendants' actions, as set forth above, the State of Texas and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXXIII
(Violation of Vermont False Claims Act)

391. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

392. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of Vt. Stat. Ann. tit. 32, §§ 630, *et seq*.

393. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to obtain payment or approval of claims by the State of Vermont, or its political subdivisions, in violation of Vt. Stat. Ann. tit. 32, § 631(a)(2).

394. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Vermont, or its political subdivisions, in violation of Vt. Stat. Ann. tit. 32, § 631(a)(10).

395. The State of Vermont, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims

and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the State or its political subdivisions.

396. As a result of Defendants' actions, as set forth above, the State of Vermont and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXXIV
(Violation of Virginia Fraud Against Taxpayers Act)

397. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

398. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the Commonwealth of Virginia, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Va. Code Ann. § 8.01-216.3(A)(1).

399. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Commonwealth of Virginia, or its political subdivisions, in violation of Va. Code Ann. § 8.01-216.3(A)(2).

400. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit

money to the Commonwealth of Virginia, or its political subdivisions, in violation of Va. Code Ann. § 8.01-216.3(A)(7).

401. The Commonwealth of Virginia, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state-funded health insurance programs.

402. As a result of Defendants' actions, as set forth above, the Commonwealth of Virginia and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXXV
(Violation of Washington Medicaid False Claims Act)

403. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

404. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment of approval, in violation of Wash. Rev. Code §§ 74.66.005, *et seq*.

405. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Wash. Rev. Code § 74.66.020(1)(a).

406. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Washington, or its political subdivisions, in violation of Wash. Rev. Code §§ 74.66.020(1)(a).

407. The State of Washington, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state-funded health insurance programs.

408. As a result of Defendants' actions, as set forth above, the State of Washington and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXXVI
(Violation of the California Insurance Fraud Protection Act,
Cal. Ins. Code §§ 1871.7(a) & (b))

409. Plaintiff re-alleges and incorporates by reference all prior paragraphs.

410. J&J knowingly employed Health Care Providers as "runners, cappers, steerers, or other persons" by paying them kickbacks to "procure clients or patients to perform or obtain services or benefits under a contract of insurance," in violation of Cal. Ins. Code § 1871.7(a) and under Cal. Bus. & Prof. Code § 650(a).

411. J&J also knowingly employed its sales representatives as "runners, cappers, steerers, or other persons" to cause ophthalmologists, opticians and other health care professionals, and their staff, to be paid kickbacks, and/or to falsify or cause said Health Care Providers to falsify health care claims, all to "procure clients or patients to perform or obtain

services or benefits under a contract of insurance," and all in violation of Cal. Ins. Code § 1871.7(a) and under Cal. Bus. & Prof. Code § 650(a).

412. Through their payment of kickbacks, the Defendants knowingly prepared, made, and/or subscribed a writing, with the intent to present or use it, or to allow it to be presented, in support of false and/or fraudulent claims in violation of Cal. Ins. Code § 1871.7(b) and Cal. Penal Code § 550(a)(5).

413. Through their payment and receipts of kickbacks, the Defendants also knowingly made or caused to be made false or fraudulent claims for the payment of a health care benefit in violation of Cal. Ins. Code § 1871.7(b) and Cal. Penal Code § 550(a)(6).

414. Through their payment and/or receipt of kickbacks, Defendants presented or caused to be presented written and/or oral statements as part of, or in support of, claims for payment or other benefit pursuant to an insurance policy, knowing that the statements contained false and/or misleading information concerning one or more material facts in violation of Cal. Ins. Code § 1871.7(b) and Cal. Penal Code § 550(b)(1).

415. Through their payment and/or receipt of kickbacks, the Defendants prepared or made written and/or oral statements that were intended to be represented to an insurer or insurance claimant in connection with, or in support of, claims for payment or other benefits pursuant to an insurance policy, knowing that the statements contained false or misleading information concerning one or more material facts in violation of Cal. Ins. Code § 1871.7(b) and Cal. Penal Code § 550(b)(2).

416. The payment and/or receipt of kickbacks as described herein has had the direct effect of greatly increasing the number of claims submitted to and paid by California MCOs for

various premium J&J products Remicade and/or Simponi Aria, thereby increasing the amount of money spent by California MCOs for these drugs.

417. J&J's payments of kickbacks induced the cooperation of Health Care Providers to evade California MCO cost containment programs, and thereby aided and/or abetted J&J's scheme to induce the dispensing of its expensive drugs. This use of kickbacks has had the direct effect of greatly increasing the number of prescriptions filled with J&J products Remicade and Simponi Aria, thereby increasing the price of said prescriptions which were then paid for or reimbursed by California MCOs.

PRAYER FOR RELIEF

WHEREFORE, Relator prays for judgment against Defendants as follows:

A. That Defendants be ordered to cease and desist from submitting or causing to be submitted any more false claims, or further violating 31 U.S.C. §§ 3729 *et seq.*; Cal. Gov't Code §§ 12650 *et seq.*; Colo. Rev. Stat. §§ 25.5-4-304 *et seq.*; Conn. Gen. Stat. tit. 4 Ch. 55e §§ 4-274 *et seq.*; Del. Code Ann. tit. 6, §§ 1201 *et seq.*; D.C. Code §§ 2-308.13 *et seq.*; Fla. Stat. §§ 68.081 *et seq.*; Ga. Code Ann. §§ 49-4-168 *et seq.*; Haw. Rev. Stat. §§ 661-21 *et seq.*; 740 Ill. Comp. Stat. §§ 175/1 *et seq.*; Ind. Code §§ 5-11-5.7 *et seq.*; Iowa Code tit. 15 §§ 685.1 *et seq.*; La. Rev. Stat. Ann. §§ 46:437.1 *et seq.*; Md. Code Ann., Health Gen. §§ 2-601 *et seq.*; Mass. Gen. Laws ch. 12, §§ 5A *et seq.*; Mich. Comp. Laws §§ 400.601 *et seq.*; Minn. Stat. §§ 15C.01 *et seq.*; Mont. Code Ann. §§ 17-8-401 *et seq.*; Nev. Rev. Stat. §§ 357.010 *et seq.*; N.H. Stat. Ann. §§ 167:61-b, *et seq.*; N.J. Stat. Ann. §§ 2A:32C-1 *et seq.*; N.M. Stat. Ann. §§ 27-14-1 *et seq.*; N.Y. State Fin. Law Art. XIII §§ 187 *et seq.*; N.C. Gen. Stat. §§ 1-605 *et seq.*; Okla. Stat. tit. 63, §§ 5053 *et seq.*; R.I. Gen. Laws §§ 9-1.1-1 *et seq.*; Tenn. Code Ann. §§ 71-5-181 *et seq.*; Tex. Hum. Res. Code Ann. §§ 36.001 *et seq.*; Tex. Hum. Res. Code. Ann. §§ 32.039 *et seq.*; Va. Code

Ann. §§ 8.01-216.1 *et seq.*; Vt. Stat. Ann. tit. 32, §§ 630, *et seq.*; and Wash Rev. Code §§ 74.66.005 *et seq.*

B. That judgment be entered in Relator's favor and against Defendants in the amount of each and every false or fraudulent claim, multiplied as provided for in 31 U.S.C. § 3729(a), plus a civil penalty of not less than five thousand ($5,500) or more than ten thousand dollars ($11,000) per claim as provided by 31 U.S.C. § 3729(a)(1), to the extent such multiplied penalties shall fairly compensate the United States of America for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

C. That Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d), Cal. Gov't Code § 12652(g)(4), Cal. Ins. Code § 1871.7(g), Colo. Rev. Stat. § 25.5-4-306(4), Conn. Gen. Stat. tit. 4 Ch. 55e § 4-278(e), Del. Code Ann. tit. 6, § 1205, D.C. Code § 2-308.15(f), Fla. Stat. § 68.085, Ga. Code Ann. § 49-4-168.2(i), Haw. Rev. Stat. § 661-27, 740 Ill. Comp. Stat. § 175/4(d), Ind. Code § 5-11-5.5-6, Iowa Code § 685.3(4)(a)(1), La. Rev. Stat. Ann. § 439.4, Md. Code Ann., Health-Gen. § 2-605, Mass. Gen. Laws ch.12, § 5F, Mich. Comp. Laws § 400.610a(9), Minn. Stat. § 15C.13, Mont. Code Ann. § 17-8-410, Nev. Rev. Stat. § 357.210, N.H. Stat. Ann § 167:61-e, N.J. Stat. Ann. § 2A:32C-7, N.M. Stat. Ann. § 27-14-9, N.Y. State Fin. Law § 190(6), N.C. Gen. Stat. § 1-610, Okla. Stat. tit. 63, § 5053.4, R.I. Gen. Laws § 9-1.1-4(d), Tenn. Code Ann. § 71-5-183(d), Tex. Hum. Res. Code Ann. § 36.110, Tex. Hum. Res. Code. Ann. § 32.039, Vt. Stat. Ann. tit. 32, § 635, Va. Code Ann. § 8.01-216.7, and Wash. Rev. Code § 74.66.070, including reasonable attorneys' fees, expenses and costs.

D. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of California or its political subdivisions multiplied as

provided for in Cal. Gov't Code § 12651(a), plus a civil penalty of not less than five thousand dollars ($5,000) per claim or more than ten thousand dollars ($10,000) per claim as provided by Cal. Gov't Code § 12651(a), to the extent such penalties shall fairly compensate the State of California or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

E. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Colorado or its political subdivisions multiplied as provided for in Colo. Rev. Stat. § 25.5-4-305(1), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each act as provided by Colo. Rev. Stat. § 25.5-4-305(1), to the extent such multiplied penalties shall fairly compensate the State of Colorado or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

F. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Connecticut multiplied as provided for in Conn. Gen. Stat. § 17b-301b(b)(2), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each act in violation of the State of Connecticut False Claims Act, as provided by Conn. Gen. Stat. § 17b-301b(b)(1), to the extent such multiplied penalties shall fairly compensate the State of Connecticut for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

G. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Delaware multiplied as provided for in Del. Code Ann. tit. 6, §1201(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) for each act in violation of the Delaware False Claims and Reporting Act, as provided by Del. Code Ann. tit. 6, §1201(a), to the extent such multiplied penalties shall fairly compensate the State of Delaware for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

H. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the District of Columbia, multiplied as provided for in D.C. Code § 2-308.14(a), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each false claim, and the costs of this civil action brought to recover such penalty and damages, as provided by D.C. Code § 2-308.14(a), to the extent such multiplied penalties shall fairly compensate the District of Columbia for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

I. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Florida or its agencies multiplied as provided for in Fla. Stat. § 68.082(2), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) for each false claim as provided by Fla. Stat. Ann. § 68.082(2), to the extent such multiplied penalties shall fairly compensate the State of Florida or its agencies for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

J. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Georgia or its political subdivisions multiplied as provided for in Ga. Code Ann. § 49-4-168.1(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) per false claim as provided by Ga. Code Ann. § 49-4-168.1(a), to the extent such multiplied penalties shall fairly compensate the State of Georgia or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

K. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Hawaii, multiplied as provided for in Haw. Rev. Stat. § 661-21(a), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) as provided by Haw. Rev. Stat. § 661-21(a), to the extent such multiplied penalties shall fairly compensate the State of Hawaii for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

L. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Illinois, multiplied as provided for in 740 Ill. Comp. Stat. § 175/3(a)(1)(A), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000), as provided by 740 Ill. Comp. Stat. § 175/3(a)(1)(A), and the costs of this civil action as provided by 740 Ill. Comp. Stat. § 175/3(a)(1)(B), to the extent such penalties shall fairly compensate the State of Illinois for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

M. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Indiana, multiplied as provided for in Ind. Code § 5-11-5.5-2(b), plus a civil penalty of at least five thousand dollars ($5,000) as provided by Ind. Code § 5-11-5.5-2(b), to the extent such penalties shall fairly compensate the State of Indiana for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

N. That judgment be entered in Relator's favor and against Defendants in the amount of damages sustained by the State of Iowa, multiplied as provided for in Iowa Code § 685.2(1), plus a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), as provided by Iowa Code § 685.2(1), to the extent such multiplied penalties shall fairly compensate the State of Iowa or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

O. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by Louisiana's medical assistance programs, multiplied as provided for in La. Rev. Stat. Ann. § 46:438.6(B)(2), plus a civil penalty of no more than ten thousand dollars ($10,000) per violation or an amount equal to three times the value of the illegal remuneration, whichever is greater, as provided for by La. Rev. Stat. Ann. § 46:438.6(B)(1), plus up to ten thousand dollars ($10,000) for each false or fraudulent claim, misrepresentation, illegal remuneration, or other prohibited act, as provided by La. Rev. Stat. Ann. § 46:438.6(C)(l)(a), plus payment of interest on the amount of the civil fines imposed pursuant to Subsection B of § 438.6 at the maximum legal rate provided by La. Civil Code Art. 2924 from the date the damage occurred to the date of repayment, as provided by La. Rev. Stat. Ann.

§ 46:438.6(C)(l)(b), to the extent such multiplied fines and penalties shall fairly compensate the State of Louisiana's medical assistance programs for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

P. That judgment be entered in Relator's favor and against Defendants in the amount of damages sustained by the State of Maryland or its political subdivisions, multiplied as provided for in Md. Code Ann., Health-Gen. § 2-602(b)(1)(ii), plus a civil penalty of not more than ten thousand dollars ($10,000) for each false claim, as provided by Md. Code Ann., Health-Gen. § 2-602(b)(1)(i), to the extent such multiplied penalties shall fairly compensate the State of Maryland or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

Q. That judgment be entered in Relator's favor and against Defendants for restitution to the Commonwealth of Massachusetts or its political subdivisions in the amount of a civil penalty of not less than five thousand dollars ($5,000) dollars and not more than ten thousand dollars ($10,000), plus three times the amount of damages, including consequential damages, sustained by Massachusetts as the result of Defendants' actions, plus the expenses of the civil action brought to recover such penalties and damages, as provided by Mass. Gen. Laws ch 12. § 5B, to the extent such penalties shall fairly compensate the Commonwealth of Massachusetts or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

R. That judgment be entered in Relator's favor and against Defendants for restitution to the State of Michigan or its political subdivisions for the value of payments or benefits provided as a result of Defendants' unlawful acts, plus a civil penalty of triple the amount of damages suffered by Michigan as a result of Defendants' unlawful conduct, as well as not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) per claim, as provided by Mich. Comp. Laws § 400.612(1), as well as the costs incurred by both Michigan and Relator, as provided by §§ 400.610a(9) and 400.610b, in order to fairly compensate the State of Michigan or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

S. That judgment be entered in Relator's favor and against Defendants for restitution to the State of Minnesota or its political subdivisions for the value of payments or benefits provided as a result of Defendants' unlawful acts, plus a civil penalty of triple the amount of damages suffered by Minnesota as a result of Defendants' unlawful conduct, as well as not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) per claim, as provided by Minn. Stat. § 15C.02(a), as well as the costs incurred by both Minnesota and Relator, as provided by Minn. Stat. § 15C.12, in order to fairly compensate Minnesota or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

T. That judgment be entered in Relator's favor and against Defendants for restitution to the State of Montana or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in Mont.

Code Ann. § 17-8-403, multiplied as provided for in Mont. Code Ann. § 17-8-403(2), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each false claim, pursuant to Mont. Code Ann. § 17-8-403(2), to the extent such multiplied penalties shall fairly compensate the State of Montana or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

U. That judgment be entered in Relator's favor and against Defendants for restitution to the State of Nevada for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in Nev. Rev. Stat. § 357.040, multiplied as provided for in Nev. Rev. Stat. § 357.040(1), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each act, pursuant to Nev. Rev. Stat. § 357.040(1), to the extent such multiplied penalties shall fairly compensate the State of Nevada for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

V. That judgment be entered in Relator's favor and against Defendants in the amount of damages sustained by the State of New Hampshire, multiplied as provided for in NH Stat. Ann § 167:61-b(I), plus a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), as provided by NH Stat. Ann § 167:61-b(I), to the extent such multiplied penalties shall fairly compensate the State of New Hampshire or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

W. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of New Jersey or its political subdivisions multiplied as

provided for in N.J. Stat. Ann. § 2A:32C-3, plus a civil penalty of not less than and not more than the civil penalties allowed under the federal False Claims Act (31 U.S.C. § 3729 *et seq.*) for each false or fraudulent claim, to the extent such multiplied penalties shall fairly compensate the State of New Jersey or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

X. That judgment be entered in Relator's favor and against Defendants for restitution to the State of New Mexico or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in N.M. Stat. Ann. § 27-14-4, multiplied as provided for in N.M. Stat. Ann. § 27-14-4, to the extent such multiplied penalties shall fairly compensate the State of New Mexico or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

Y. That judgment be entered in Relator's favor and against Defendants for restitution to the State of New York or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in N.Y. State Fin. Law § 189(1), multiplied as provided for in N.Y. State Fin. Law § 189(1), plus a civil penalty of not less than six thousand dollars ($6,000) or more than twelve thousand dollars ($12,000) for each false claim, pursuant to N.Y. State Fin. Law § 189(1), to the extent such multiplied penalties shall fairly compensate the State of New York or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

Z. That judgment be entered in Relator's favor and against Defendants for restitution to the State of North Carolina for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in N.C. Gen. Stat. § 1-607, multiplied as provided for in N.C. Gen. Stat. § 1-607(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) as provided by N.C. Gen. Stat. § 1-607(a), to the extent such multiplied penalties shall fairly compensate the State of North Carolina for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

AA. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Oklahoma or its political subdivisions multiplied as provided for in Okla. Stat. tit. 63, § 5053.1(B), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) as provided by Okla. Stat. tit. 63, § 5053.1(B), to the extent such multiplied penalties shall fairly compensate the State of Oklahoma or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

BB. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Rhode Island or its political subdivisions multiplied as provided for in R.I. Gen. Laws § 9-1.1-3(a), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) per claim as provided by R.I. Gen. Laws § 9-1,1-3(a), to the extent such multiplied penalties shall fairly compensate the State of Rhode Island or its political subdivisions for losses resulting from the various schemes

undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

CC. That judgment be entered in Relator's favor and against Defendants for restitution to the State of Tennessee for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in Tenn. Code Ann. § 71-5-182, multiplied as provided for in Tenn. Code Ann. § 71-5-182(a)(l), plus a civil penalty of not less than five thousand dollars ($5,000) or more than twenty-five thousand dollars ($25,000) pursuant to Tenn. Code Ann. § 71-5-182(a)(l), to the extent such multiplied penalties shall fairly compensate the State of Tennessee for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

DD. That judgment be entered in Relator's favor and against Defendants for restitution to the State of Texas for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in Tex. Hum. Res. Code Ann. § 36.052(a) and Tex. Hum. Res. Code Ann. § 32.039, multiplied as provided for in Tex. Hum. Res. Code Ann. § 36.052(a)(4), the interest on the value of such payments or benefits at the prejudgment interest rate in effect on the day the payment or benefit was paid or received, for the period from the date the payment or benefit was paid or received to the date that restitution is made to the State of Texas, pursuant to Tex. Hum. Res. Code Ann. § 36.052(a)(2), plus an administrative penalty not to exceed twice the amount paid, as provided by Tex. Hum. Res. Code. Ann. § 32.039(c)(2), plus a civil penalty of not less than five thousand dollars ($5,000) or more than fifteen thousand dollars ($15,000) for each unlawful act committed that resulted in injury to an elderly or disabled person, and of not less than one thousand dollars ($1,000) or more than ten thousand dollars ($10,000) for each unlawful act committed that did not result in injury to an

elderly or disabled person, pursuant to Tex. Hum. Res. Code Ann. §§ 36.052(a)(3)(A) & (B) and Tex. Hum. Res. Code. Ann. § 32.039(c)(2)(A) & (B), to the extent such multiplied penalties shall fairly compensate the State of Texas for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

EE. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Vermont or its political subdivisions, multiplied as provided for in Vt. Stat. Ann. tit. 32, § 631(b)(2), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) and not more than eleven thousand dollars ($11,000) for each claim, as provided by Vt. Stat. Ann. tit. 32, § 631(b)(1), as well as the costs incurred by the State of Vermont, as provided by Vt. Stat. Ann. tit. 32, § 631(b)(3), in order to fairly compensate the State of Vermont or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for s Vt. Stat. Ann. tit. 32, specific claims to be identified at trial after full discovery;

FF. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the Commonwealth of Virginia, multiplied as provided for in Va. Code Ann. § 8.01-216.3(A), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) as provided by Va. Code Ann. § 8.01-216.3(A), to the extent such multiplied penalties shall fairly compensate the Commonwealth of Virginia for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

GG. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Washington or its political subdivisions multiplied as provided for in Wash. Rev. Code § 74.66.020(1), plus a civil penalty of not less than ten thousand nine hundred fifty-seven dollars ($10,957) and not more than twenty-one thousand nine hundred sixteen dollars ($21,916) per claim as provided by Wash. Rev. Code § 74.66.020(1), to the extent such penalties shall fairly compensate the State of Washington or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

HH. That civil penalties of $10,000 be imposed, pursuant to Cal. Ins. Code § 1871.7(b), for each and every fraudulent claim that Defendants presented or caused to be presented to an insurance Company;

II. That Defendants pay, pursuant to Cal. Ins. Code § 1871.7(b), three times the amount of each claim that Defendants presented or caused to be presented to an insurance company; that Defendants pay damages sufficient to disgorge their unlawful profit and provide restitution for their fraudulent conduct;

JJ. That the Court, pursuant to Cal. Ins. Code§ 1871.7(b), issue an order preventing the Defendants from transferring, concealing, or dissipating the proceeds of its illegal conduct;

KK. That pre- and post-judgment interest be awarded, along with reasonable attorneys' fees, costs and expenses which were necessarily incurred in bringing and pressing this case, pursuant to Cal. Ins. Code § 1871.7(g)(1)(A)(iii)(I);

LL. That Defendants be ordered to disgorge all sums by which they have been enriched unjustly by their wrongful conduct;

MM. That judgment be granted for Relator against Defendants for all costs, including, but not limited to, court costs, expert fees and all attorneys' fees incurred by Relator in the prosecution of this suit;

NN. That Relator be granted such other and further relief as the Court deems just and proper;

OO. That the Court issue an order enjoining the Defendants from continuing to engage in the fraudulent conduct alleged herein; and

PP. That this Court award such further relief as it deems just and proper.

JURY TRIAL DEMAND

Relator demands a trial by jury of all issues so triable.

Dated: September 4, 2018

Respectfully submitted,

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